**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| DePuy Mitek, Inc.<br>a Massachusetts Corporation<br><br>Plaintiff,<br><br>v.<br><br>Arthrex, Inc.<br>a Delaware Corporation<br><br>Defendant. | ) | Civil Action No. 04-12457 PBS |

**<u>DEFENDANTS ARTHREX, INC.'S AND PEARSALLS, LTD.'S OPENING BRIEF ON CLAIM CONSTRUCTION</u>**

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## I. INTRODUCTION

This is a patent infringement action involving U.S. Patent No. 5,314,446 ("the '446 patent"). Plaintiff DePuy Mitek, Inc. ("DePuy Mitek") is alleging that defendants Arthrex, Inc. ("Arthrex") and Pearsalls, Limited ("Pearsalls") (together, "defendants") infringe various claims of the '446 patent[1] by their respective activities in connection with FiberWire® surgical suture.

In *Markman v. Westview Instruments, Inc*., 517 U.S. 370, 372 (1996), the Supreme Court held that the meaning of patent terms is a matter of law for the Court to decide. Accordingly, pursuant to *Markman* and to the Court's Order, dated June 19, 2006, entered in this case, defendants submit this opening brief on claim construction explaining their position as to the interpretation of the claim terms at issue in this litigation.

## II. STATEMENT OF FACTS

Arthrex's accused FiberWire® suture is the first high-strength suture to be introduced in the marketplace. Ex. 1 at 146:7-14. In fact, when it was first introduced in 2001, FiberWire was more than twice as strong as the conventional sutures on the market. Ex. 2 at 8. FiberWire attributes its high-strength to ultra high molecular weight polyethylene ("UHMWPE"), one of the strongest synthetic materials that has ever been created. Ex. 3 at § 1. The UHMWPE is braided together with a polyester known as PET.

The '446 patent, to the contrary, does not mention a high-strength suture as being one of the goals of the invention. Rather, the '446 patent recognizes that some suture strength will be sacrificed. Ex. 4 at col. 2, ll. 31-37; col. 2, l. 66. The '446 patent specification recognizes that there is a tradeoff between suture strength on the one hand and pliability on the other. Ex. 4 at col. 2, ll. 22-28. The '446 patent opts to concentrate on pliability and handleability improvement, stating that the goal is to improve pliability and handleability without appreciably

[1] The asserted claims of the '446 patent are claims 1, 2, 8, 9 and 12.

sacrificing its physical properties, such as physical strength or knot security. Ex. 4 at col. 2, ll. 31-37; col. 2, l. 66. This was also confirmed by Dr. Steckel, one of the inventors of the '446 patent. Dr. Steckel stated that the goal was to produce a suture which maintained the strength of Ethibond (an existing suture made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 5 at 103:23-104:17. Whereas the goal of the inventors was to *maintain* the strength of Ethibond, with the acknowledgement that some sacrifice in physical strength may be necessary, FiberWire is the exact opposite. FiberWire makes no sacrifice of physical strength – to the contrary, FiberWire provides superior strength as compared with Ethibond. Ex. 2 at 8.

In February 1992, Ethicon filed the patent application that eventually became the '446 patent.

## III. THE '446 PATENT AND PROSECUTION HISTORY

The specification begins with a summary of prior suture development, explaining that multi-filament braided sutures were developed to improve suture pliability compared to monofilament, unbraided sutures. Ex. 4 at col. 1, ll. 5-25. The specification cautioned, however, that mechanisms, *such as coating*, will adversely affect braid mobility. The specification explains that "the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid." Ex. 4 at col. 1, ll. 26-29. The first example presented is coating, which "improve[s] handling properties," but at the expense of braid pliability. Ex. 4 at col. 1, ll. 29-31.

The specification explains that the past attempts in the prior art "have overlooked the importance of fiber-fiber friction and its impact of fiber mobility and braid pliability." Ex. 4 at col. 2, ll. 14-17. The specification suggests that while a braid made entirely of "highly lubricious polymers" can be used to make a highly pliable braid, such a braid "will be relatively weak and

unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments." Ex. 4 at col. 2, ll. 22-28. This theme that lubricious polymers are too weak for suture usage is repeated when the specification explains that a "volume fraction of lubricating yarns . . . above 80% may adversely affect the overall strength of the braid." Ex. 4 at col. 4, ll. 50-54.

The specification then explains that the proposed solution is to have a suture comprised of a heterogeneous braid made of two different fiber forming materials which exhibits "improved pliability[2] and handling properties[3] . . . without appreciably sacrificing" [the suture's] physical properties," (Ex. 4 at col. 2, lines 31-37), namely its "physical strength and knot security." Ex. 4 at col. 2, l. 66. This proposed solution is repeated throughout the specification. Ex. 4 at col. 2, ll. 62-66; col. 6, ll. 7-8.

The '446 patent relies heavily on what is called the "rule of mixtures" to attempt to demonstrate that this combination is an improvement in the art. Ex. 4 at col. 8, ll. 22, 35 and 38. The point made by the inventors is that gains in pliability and handleability by using the combination of highly pliable and lubricious, but relatively weak, materials with a stronger material outweighs the loss of suture strength.

The specification also discusses the use of coating. It explains that coating, if desired, can be added "to further improve the handleability and knot tiedown performance of the braid. It also explains that if the braid "possesses a significant [amount] of the lubricious yarns, the conventional coating may be eliminated saving expense as well as the associated braid stiffening." Ex. 4 at col. 6, ll. 5-17.

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2 The '446 patent specifically refers to "pliability" in connection with "resistance to bending," (Ex.4 at col. 1, ll., 11-15, 24) and "bending rigidity," (Ex. 4 at col. 6, ll. 44-45, col. 8, Table, ll. 44-46), which are the inverse of pliability.

3 One handling property specifically identified in the patent is "knot tie down." Ex. 4 at col. 6., ll. 7-8.

In short, the specification teaches several things. First, highly pliable and lubricious yarns are too weak to use alone; that is, the suture would break. Second, using two different materials braided together is designed to improve the handleability and pliability aspects of a suture without significantly hurting the overall braid strength. Third, while adding coating to a braid is helpful for knot tie down and other handleability characteristics, it creates problems with pliability as well as added costs. The use of coating can be avoided, and the downsides it brings can be eliminated if a sufficient amount of the lubricious material is used.

Seven polymers (PTFE, FEP, PFA, PVDF, PETFE, PP and PE) are identified as the yarns that are included for lubricity so as to improve the overall pliability of the braid. Ex. 4 at col. 4, ll. 11-27. Three materials, PET, nylon and aramid, are identified as the ones that could be used for improving the strength of the braid. Ex. 4 at col. 4, ll. 35-40. Notably, the term PE is never associated with the "strength" yarns. This dichotomy, between lubricious polymers for improving overall pliability and polymers added for improving the strength of the braid, is carried into the claims.

Claim 1 of the '446 patent is to a surgical suture "consisting essentially of" a heterogeneous braid of a first and second set of yarns in a sterilized and braided construction. Claim 1 further defines the first set of yarns as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE – the same materials identified in the specification as being pliable and lubricious. The claim defines the second set of yarns as one of PET, nylon and aramid – the same materials identified in the specification as being added for improving the strength of the braid.[4]

As the application for the '446 patent was originally filed, there were two sets of claims – one set for heterogeneous braids and a second set for surgical sutures made from

[4] Since the other asserted claims ultimately are dependent on claim 1 – that is, they have every limitation of claim1 plus additional limitations – they include the limitations discussed above.

heterogeneous braids. Ex. 6 at 18-20. Early on, Ethicon was required to elect which set of claims it wanted to prosecute. The election was required because the patent examiner observed that they were distinct sets of claims where one set – the heterogeneous braid claims – were an intermediate product that could be used to make surgical sutures (the second set of claims) as well as other products. Ex. 7 at 2. Ethicon elected to pursue the surgical suture claims. Ex. 7. As originally filed, the first suture claim was very broad. It required only that the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact. The specific materials were not part of the claim and it did not include the "consisting essentially of" limitation. Ex. 6 at 18-20.

In the first Office Action, the examiner rejected the suture claims based on U.K. patent application no. 2,218312A to Burgess ("the Burgess application") (Ex. 8). The Burgess application disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE[5] and either nylon or polyester. Ex. 8. The examiner rejected the suture claims, explaining that the requirements for fishing line were similar to those of suture. Ex. 7 at 4.

In distinguishing the '446 patent from the Burgess application, Ethicon responded that because of its braided construction, "the fishing line of Burgess would have poor knot strength properties." [Emphasis in original.] Ethicon explained that the Burgess braid combination would have poor knot strength properties because it included UHMWPE. Ethicon stated that UHMWPE "gives the line minimal stretchability." [Emphasis in original.] Ex. 9 at 2. Ethicon further explained that "although this thread has great strength properties, it suffers from low elongation and, in turn, poor knot strength properties." [Emphasis in original.] Ethicon concluded that, as a result of the different requirements of fishing line and suture, one should not look to the fishing line art. But Ethicon went a step further. Ethicon also told the Patent Office

[5] The Burgess application uses the term high tensile polythene, the European term for UHMWPE.

that "[e]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are presented by the Burgess application], one would inevitably design an unacceptable suture." Ex. 9 at 3-4. In other words, Ethicon argued that the braid combination disclosed in Burgess – UHMWPE and polyester or nylon – was not an acceptable combination for a suture. Ethicon argued that it was not acceptable because the attributes of UHMWPE were not what one would want in a suture, a position that was crucial in overcoming the examiner's rejection.

Later during prosecution, Ethicon made two pertinent amendments to the claims. First, it abandoned the broad claims that required only that that braid be made of two dissimilar materials. Ex. 10 at 1. The allowed claims were limited to what is known as "Markush groups," where the dissimilar materials had to be from the group of specifically-named materials.[6] In the allowed claims, the first set of yarns were from a group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The second set of yarns were from the group consisting of PET, nylon and aramid. Ex. 10 at 1.

Second, the preamble of the claims was amended to change the term "comprising" to "consisting essentially of." Ex. 10 at 1. This amendment served to significantly narrow the claims. "Comprising" is an open term; infringement is shown as long as the accused device has every limitation of the claims; infringement is not avoided if the accused device has other additional materials. *See, e.g.*, *Free Motion Fitness, Inc. v. Cybex Intern, Inc.*, 423 F.3d 1343, 1353 (Fed. Cir. 2005). "Consisting essentially of" is not an open term. Infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003).

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6 A Markush group is one in which the substances grouped are related in some way. *See, e.g.* Manual of Patent Examining Procedure at § 2173.05(h).

## IV. LEGAL STANDARDS FOR CLAIM CONSTRUCTION

In a patent infringement case, the court has the "power and obligation to construe as a matter of law the meaning of language used in the patent claim." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). In affirming this decision, the Supreme Court held "that the construction of a patent, including terms of art within its claims, is exclusively within the province of the court." *Markman v. Westview Instruments, Inc*., 517 U.S. 370, 372 (1996). "As a general rule, patent claims must be interpreted to sustain their validity if possible." *Quantum Corp. v. Rodime PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995).

The scope of any patent's protection is defined by its patent claims. *See Phillips v. AWH Corp*., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The first step in any infringement analysis is to determine a patent claims' meaning and scope. *Markman*, 52 F.3d at 976-977.

In *Phillips*, the *en banc* Federal Circuit endorsed the uncontroversial maxim that the words of a claim are generally given their ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. *Phillips*, 415 F.3d at 1313. The court, however, heard the case *en banc* to resolve a dispute regarding two competing methodologies on how to accomplish the task. In its decision, the Federal Circuit endorsed the approach that started the claim construction analysis with the intrinsic evidence - the claims, the written specification and, if appropriate, the prosecution history - rather than the approach enunciated in *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.2d 1193 (Fed. Cir. 2002), which began the analysis with dictionary definitions and only permitted consideration of the specification and prosecution history for a limited purpose.

In *Phillips*, the *en banc* Federal Circuit emphasized that a disputed claim term can never be viewed in a vacuum, but rather must always be interpreted in the context of the written description and the prosecution history. *Phillips*, 415 F.3d at 1313. The court reiterated its prior

holding from *Vitronics Corp v. Conceptronic, Inc*., 90 F.3d 1576 (Fed. Cir. 1996), that "the specification is always highly relevant to the claim construction analysis . . . and that it is the single best guide to the meaning of a disputed term." *Id.* at 1582. The court also stressed the public notice function of patents. It cautioned that undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of "the indisputable public records consisting of the claims, the specification and the prosecution history." *Phillips*, 415 F.3d at 1319. After discussing the statutory basis for the specification's importance, the Federal Circuit concluded:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

*Phillips*, 415 F.3d at 1316, quoting *Renishaw PLC v. Marposs Societa'per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

The Federal Circuit approved the use of the prosecution history, also part of the intrinsic evidence, in the claim construction analysis. The court observed that the prosecution history can provide evidence of how the PTO and the inventor understood the patent and that like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent. *Phillips*, 415 F.3d at 1317.

While the Federal Circuit held that extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, could be used, the court also held that such evidence "is 'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Id*. at 1317 quoting *C.R. Bard, Inc. v. U.S. Surgical Corp*., 388

F.3d 858, 862 (Fed. Cir. 2004), quoting *Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1316, 1318 (Fed. Cir. 2004).[7]

The Federal Circuit was critical of the *Texas Digital* approach and was particularly cautious about the use of dictionary definitions, stating that "[h]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term . . . into the meaning of the term in the abstract" and out of its proper context. *Id*. at 1321. The use of dictionary definitions can be troublesome because the applicant "did not create the dictionary to describe the invention" and thus, "there may be a disconnect between the patentee's responsibility to describe and claim his invention, and the dictionary editors' objective of aggregating all possible definitions for particular words." *Id*. at 1321.

Unlike the phrase "comprising," the phrase "consisting essentially of" in a patent claim is not an open term. Infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). To determine the basic and novel characteristics, one need look no further than the patent specification. *Id*.

## V. INTERPRETATION OF DISPUTED CLAIM TERMS

DePuy Mitek asserts infringement of independent claim 1 and dependent claims 2, 8, 9 and 12. Claim 1 is as follows:

> 1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a

[7] The court explained that there were several reasons why extrinsic evidence was less reliable than intrinsic evidence. Among other things, it does not have the virtue of being created at the time of prosecution for the purpose of explaining the patent's scope and meaning, such evidence may not be written for a person of ordinary skill, it can be biased because it is created at the time of and for the purpose of litigation, extrinsic evidence is boundless and each party in litigation will naturally choose the evidence most favorable to its cause and extrinsic evidence poses that it will be used to change the meaning expressed in the public record and thus undermine the public notice function of patents. *Phillips*, 415 F.3d at 1319.

sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

The parties submit for the Court's construction the two disputed terms which appear in all of the asserted claims of the '446 patent.[8] These two terms, highlighted above, are "PE" and "consisting essentially of," including an identity of the "basic and novel characteristics of the claimed invention."[9]

A. "PE"

| Claim Term | Construction |
|---|---|
| PE | General purpose polyethylene. |

One of the principal issues in this case is whether the term PE, as it appears in the asserted claims of the '446 patent, includes UHMWPE, the specialized polymer that provides FiberWire® suture with its superior strength. It should come as no surprise that DePuy Mitek seeks to have the term "PE" construed such that it includes UHMWPE. As we show below, DePuy Mitek can come to that conclusion by relying almost exclusively on dictionary definitions

8 Since the terms appear in the independent claim, they are also part of the dependent claims because a dependent claim includes all the limitations of the independent claim plus additional limitations. *See, e.g. Robotic Vision Sys., Inc. v. View Engineering, Inc.,* 189 F.3d 1370, 1376 (Fed. Cir. 1999).

9 The parties agree on the construction of the other two claim terms requiring construction. Specifically, the parties agree that the term "direct intertwining contact," means "the mechanical interlocking or weaving of the individual yarns that make up the suture braid." The parties also agree that the term "volume fraction of the first set of yarns in the braided sheath and core" means "the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross-sectional area of all the yarns in the surgical suture."

and by essentially ignoring the specification and prosecution history of the ‘446 patent, the same approach rejected by the *en banc* Federal Circuit in Phillips.

Defendants, on the other hand, believe the term “PE” in the claims refers to general purpose PE which excludes UHMWPE. As explained below, a proper review of the specification and prosecution history -- the precise approach endorsed by the Federal Circuit in *Phillips*, 415 F.3d at 1313 -- leaves no doubt that the applicants did not believe that UHMWPE is a material that falls within its invention and the meaning of the term “PE.”

PE is one of the seven polymers listed in the first set of yarns of claim 1. The specification describes these same seven polymers as “lubricating yarns to improve the overall pliability” of the braid. Ex. 4 at col. 4, ll. 11-27. This theme is repeated throughout the specification. The specification unambiguously states that a braid made solely of “highly lubricious yarns” will result in “a highly pliable braid.” Ex. 4 at col. 2, ll. 22-24. Likewise, the examples given in the patent demonstrate that a lubricious yarn is highly pliable and adds more pliability to the braid than expected. Ex. 4 at col. 7, ll. 26-35, 54-64; col. 8, ll. 36-49.

This pliability description is the polar opposite of UHMWPE. The evidence in this case indisputably establishes that UHMWPE is stiff and *not* pliable. DePuy Mitek’s own expert, Dr. Brookstein, acknowledged this fact in his report. Ex. 11 at ¶ 56. The stated purpose in the patent is for the first set of yarns (including “PE”) to provide improved pliability. It simply makes no sense to construe the term “PE” to include a product that makes the suture too stiff -- the exact *opposite* effect as that described in the patent.

But there is much more. The specification teaches that while a braid made entirely of lubricious materials (such as the materials in the first group) would make a highly pliable braid, such a braid “will be relatively weak and unusable.” Ex. 4 at col. 2, ll. 22-25. This is why the specification teaches that there is a tradeoff between braid strength and pliability – the lubricious

materials have good pliability, but poor braid strength. The notion that the lubricious polymers are too weak for suture usage is repeated when the specification cautions against using more than about 80% of the lubricious yarns because such usage "may adversely affect the overall strength of the braid." Ex. 4 at col. 4, ll. 50-54.

The description of the first and second groups of yarns continues this theme. The specification teaches that a yarn from the second group of yarns needs to be added "to provide improved strength to the heterogeneous braid." Ex. 4 at col. 4, ll. 33-36. The reason that a "strength" yarn is needed is obvious -- the "pliable" yarns of the first set are too weak, just as the specification teaches. Ex. 4 at col. 2, ll. 22-25; col. 4, ll. 52-54.[10]

Once again, it would make no sense to include UHMWPE within the meaning of "PE. Unlike general purpose PE, UHMWPE is an incredibly strong material, one of the strongest materials known to man. It simply is not the kind of material which must be balanced against strong materials to achieve an acceptable suture. It simply makes no sense to include such a strong material where the patent teaches the exact opposite.

Notably, while PE is included in the group of seven lubricious materials identified for improving pliability, PE is *not* included in the group of materials identified for strength. Nor is the term PE ever associated with the "strength" yarns in the specification of the '446 patent. If PE included UHMWPE, one would have expected to see "PE" appear in the strength list. At a bare minimum, one would have expected to see *some* mention in the patent the "PE" could also

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[10] That the '446 patent considers the lubricous materials to be relatively weak is also confirmed by the tests described in the specification. For example, the Table depicts results for a multifilament braid made entirely (*i.e.*, 100 %) of a lubricious first fiber-forming material (*i.e.* CONTROL II made up of 100% PTFE). This braid was the weakest of the four braids tested, which is entirely consistent with the teachings of the specification.

Moreover, the '446 patent relies heavily on what it calls the "rule of mixtures" to explain that gains in pliability and handleability by using the combination of lubricious, but relatively weak materials (*i.e.* the seven lubricious polymers) with a stronger material (i.e., the three strength materials) outweighs the loss of suture strength realized due to the lubricious materials.

impart strength. This is particularly true in light of the fact that Ethicon and the inventors knew that UHMWPE has great strength. Inventor Steckel testified that he knew during the development work that lead to the '446 patent that UHMWPE had great strength. Ex. 5 at 190:12-191:3. Likewise, when responding to an office action during prosecution, Ethicon acknowledged that UHMWPE "has great strength properties." Ex. 9 at 2. There is a plain and simple reason that there is absolutely no mention of "PE" having strength; UHMWPE was the furthest thing from the applicants' minds when they described their invention.

As the Federal Circuit has instructed on several occasions, [t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction; *Phillips*, 415 F.3d at 1316; *Renishaw*, 158 F.3d at 1250. Here, the interpretation of "PE" that naturally aligns with the patent's description of the invention is general purpose PE and *not* UHMWPE.

If there were any doubt – and there is none – it is categorically removed by a review of Ethicon's arguments against UHMWPE in the prosecution history, which is part of the intrinsic evidence that should be consulted in determining the meaning of claim terms.

As mentioned above, during prosecution of the '446 patent, the examiner rejected the suture claims based on the Burgess application, which disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester. Ethicon argued the Burgess braid would make a poor suture. In particular, the combination would be poor *because it contained UHMWPE*, a product with "minimal stretchability" and which "suffers from poor elongation." Ex. 9 at 2-3. Ethicon concluded by stating that "[e]ven if one were to look to the fishing line art, *one would inevitably design an unacceptable suture*." Ex. 9 at 3-4. [Emphasis added.] In other words, Ethicon told the patent examiner, and be extension the public, that the combination disclosed in Burgess – UHMWPE and polyester or

nylon – would *not* make an acceptable suture. And the reason that the combination would be unacceptable was because it contained UHMWPE.

The fact is that UHMPE and general purpose PE are fundamentally very different materials. They are used for different purposes, and one can not be substituted for the other. Ex. 12 at 22. General purpose polyethylene has been around for decades and established itself as a general purpose commodity polymer. Ex. 3 at § 1. Since its introduction in fiber form in 1985, UHMWPE, to the contrary, has been considered a specialized high performance product. Ex. 3 at § 1. General purpose polyethylene and UHMWPE are simply not substitutes for each other. Ex. 12 at 22. Moreover, the key structural characteristics – molecular weight and molecular structure – of UHMWPE are very different than that of general purpose PE. Ex. 3 at § 2. UHMWPE has a molecular weight in the range of 1 to 5 million, whereas general purpose PE has a molecular weight in the range of 50,000 to several hundred thousand. UHMWPE also exhibits a much higher degree of crystalline orientation and crystalline content as compared with general purpose PE. These stark differences in molecular structure are the basis for UHMWPE's superior strength characteristics. Ex. 3 at § 2.

Despite all of the above, and contrary to the clear teachings of the '446 patent, DePuy Mitek has asserted that the term "PE" means "all types of polyethylene (PE) including ultra high molecular weight polyethylene." Ex. 12 at ¶ 27; Ex. 13 at ¶ 28.

The only way DePuy Mitek comes to this conclusion is by essentially ignoring the clear teachings of its own specification. DePuy Mitek must ignore the specification since it reveals the truth about what the term PE means in the context of the '446 patent – i.e., that it includes general purpose polyethylene, but does not include UHMWPE. Even DePuy Mitek's own expert initially admitted this. Dr. Hermes' own first impression when reading the '446

patent was that it "seem[ed] to teach away from UHMWPE." Ex. 14; Ex. 15 at 336:23-23. Dr. Hermes' first impression was entirely correct.

Undaunted by the truth, however, DePuy Mitek forges ahead and seeks to improperly construe the term PE through the use of extrinsic evidence in the form of technical treatises that take the claim terms completely out of the context in which they were written and intended -- the *Texas Digital* approach. As described above, however, this approach was resoundingly rejected by the Federal Circuit in the landmark *Phillips* decision.

The *Phillips* court warned, "[h]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term . . . into the meaning of the term in the abstract" and out of its proper context. *Id*. at 1321. The court further reasoned that the use of dictionary definitions can be troublesome because the applicant "did not create the dictionary to describe the invention" and thus, "there may be a disconnect between the patentee's responsibility to describe and claim his invention, and the dictionary editors' objective of aggregating all possible definitions for particular words." *Id*. at 1321.

The "disconnect" that troubled the Federal Circuit is the very basis for DePuy Mitek's claim construction. For example, DePuy Mitek's expert, Dr. Hermes, points to a technical treatise – entirely divorced from the context of the '446 patent – as supporting the assertion that the term "PE," as it appears in the '446 patent, is the generic name for all types of PE, including UHMWPE. The same treatise Dr. Hermes relies upon, however, expresses the very same concerns stated by the *Phillips* court 18 years later. The treatise states that so-called source-based nomenclatures have "serious deficiencies," and predicts that as a result there will be a gradual shift "away from starting materials and toward the structure of the macromolecules." Ex. 16 at 193. When confronted with this concern and prediction expressed in the same treatise he relied upon, Dr. Hermes could only state that that was the opinions of the authors and that he

did not have enough knowledge to disagree with those authors. Ex. 15 at 246:25 – 247:19. This is the approach the *Phillips* court warned about.

As made clear by the entirety of the intrinsic evidence – *i.e*., the specification and the prosecution history – when the inventors used the term "PE," they intended to mean general purpose polyethylene and not UHMWPE. Even DePuy Mitek's own expert, on his initial reading of the patent, recognized that the specification "seems to teach away from UHMWPE." For all the above reasons, Defendants' proposed construction should be adopted.

B. "Consisting essentially of"

| Claim Term | Construction |
|---|---|
| Consisting essentially of | i) The claimed surgical suture excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention.<br><br>ii) The basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. |

As described above, it is well settled that the transitional phrase "consisting essentially of," as it appears in the asserted claims of the '446 patent, is construed to mean that infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp*., 344 F.3d at 1239. The parties do not appear to dispute this basic principle. The parties do dispute, however, the identity of the "basic and novel characteristics of the claimed invention." As the Federal Circuit stated in *AK Steel*, one need look no further than the specification in order to make that determination. *Id*. at 1239. This case is no different.

In making this determination, the focus, of course, starts with the claims because the claims define the scope of the protected invention. Here, the claims are not merely to two dissimilar materials braided together,[11] but rather to the two groups with specific materials for each group (PTFE, FEP, PFA, PVDF, PETFE, PP and PE for the first group; PET, nylon and aramid for the second group). Thus, the issue is what does the specification attribute as the basic and novel characteristics for a suture braid made of these specific materials.

Focusing on the purpose of the recited materials, the specification of the '446 patent identifies the basic and novel characteristics of the claimed invention as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification, both when referring to the essential idea behind the patent and when discussing the recited materials directly. Ex. 4 at col. 2, ll. 29 – 37; ll. 62 – 66; col. 4, ll. 11-40; col. 6, ll. 7 – 8. Matthew Goodwin, the attorney who prosecuted the application for Ethicon, also confirmed this was the basic aspect of the invention. Ex. 17 at 110:14-20.[12]

As previously mentioned, the specification describes that there is a tradeoff between braid strength and pliability. In the specification, this tradeoff is advantageous because the gains achieved in pliability and handleability outweighs the loss of suture strength resulting from combining a weaker, pliable material with the stronger material. According to the specification,

---

[11] As originally filed, the application included a broad claim of two dissimilar fibers braided together without specifying any specific materials. Ex. 6. That broad claim, however, was abandoned during prosecution. Ex. 10 at 1. Language in the patent specification that relates to this broad abandoned claim cannot serve as a basis for determining the basic and novel characteristics of the narrower claims.

[12] This is also consistent with Dr. Steckel's testimony that the goal was to improve the handleability and pliability to make the suture more like silk while maintaining the strength of the existing Ethibond polyester suture. Ex. 5 at 103:23-104:17.

the resulting suture is one with improved handleability and pliability performance without significantly sacrificing its physical properties. Ex. 4 at col. 2, ll. 31-37; col. 2, l. 66.

Improved pliability and handleability on the one hand, with a minimal reduction in strength on the other hand are the characteristics attributed to the specific materials recited in the claims. The first set of yarns is included to improve pliability and surface lubricity. But because such yarns are weak, a strength component is added by a yarn of the second group. Ex. 4 at col. 2, ll. 22-25; col. 4, ll. 11-40.

Accordingly, by reviewing the specification, it becomes evident that the basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. We ask that the Court adopt this construction.

## VI. CONCLUSION

For all the foregoing reasons, defendants request that the Court adopt the claim interpretations contained herein.

Dated: August 11, 2006

Respectfully submitted,

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Counsel for Defendants
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## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Defendants Arthrex, Inc.'s and Pearsalls, Ltd.'s Opening Brief on Claim Construction was served, via the Court's email notification system on the following counsel for Plaintiff on the 11th day of August 2006:

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# EXHIBIT 1

DISK ENCLOSED



IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

C.A. No. 04-12457 PBS

ORIGINAL

* * * * * * * * * * * * * *

DePUY MITEK, INC., *

Plaintiff *

v. *

ARTHREX, INC., a Delaware *

corporation, *

Defendant *

* * * * * * * * * * * * * *

VOLUME I

PAGES 1-245

DEPOSITION OF DePUY MITEK, INC. by SHELBY COOK KORNBLUTH, a witness called on behalf of the Defendant, pursuant to the Federal Rules of Civil Procedure, before Jessica L. Williamson, Registered Merit Reporter, Certified Realtime Reporter and Notary Public in and for the Commonwealth of Massachusetts, at the Hilton Hotel, 25 Allied Drive, Dedham, Massachusetts, on Tuesday, November 15, 2005, commencing at 9:01 a.m.

Q. **And which one did you choose?**
A. The copolymer of caprolactone and glycolide.
Q. **And is that called NVC?**
A. Yes.
Q. **Did Ethicon in making these recommendations describe to you the differences between those two coatings?**
A. I don't recall.
Q. **Did you have any discussions with Ethicon as to why there would be a coating?**
A. No.
Q. **Well, why is there a coating on -- there is a coating on the Orthocord?**
A. Yes.
Q. **Why is there a coating on the product?**
A. To help with knot sliding.
Q. **What do you mean when you say "To help with knot sliding"?**
A. To help the knot slide down into the joint so that it cinches tightly. It -- you want the knot to travel down the suture.
Q. **Okay.**
A. And it helps with that traveling down the suture.
Q. **What do you mean when you say "it helps with**

A. -- I can't remember. Lupine has Panacryl. I can't remember the others. I think Spiralok -- I can't say.

**Q. What is Ethibond?**

A. Polyester suture.

**Q. And all polyester?**

A. Yes.

**Q. Does it have a coating?**

A. Yes.

**Q. And do you know what coating it has?**

A. Polybutylate.

**Q. And who makes it?**

A. Ethicon.

**Q. All right. And what is Panacryl?**

A. Panacryl is a copolymer of glycolide. It's PGA and PLA, so polyglycolic acid and polylactic acid.

**Q. Are either one of those a polyester?**

A. I can't remember. I'll have to look at the chemical composition.

**Q. Why is Panacryl used for some of the products?**

A. Because it's an absorbable suture.

**Q. And Ethibond is not?**

A. Correct.

**Q. Ethibond is not considered a high-strength suture?**

A. No.

**Q. Panacryl's not considered a high-strength suture?**

A. No.

**Q. Okay. Who was the first company to sell a high-strength suture?**

MR. FALKE: Objection, outside the scope of the notice. You can answer if you know.

A. I believe it was Arthrex.

**Q. And that was the Fiberwire product?**

A. Yes.

**Q. Isn't it correct that DePuy Mitek wanted to develop a high-strength suture to compete with Fiberwire?**

MR. FALKE: Objection, outside the scope of the notice.

A. Yes.

**Q. Is it also true that DePuy Mitek considered that they were losing their competitive edge in the marketplace if they did not develop a high-strength suture?**

MR. FALKE: Objection, outside the

scope of the notice.

A. Yes.

**Q. And is it true that DePuy Mitek considered Fiberwire to be a potentially significant threat?**

MR. FALKE: Objection, outside the scope of the notice.

A. Yes.

**Q. And is it correct that DePuy Mitek believed that it couldn't meet its marketing objectives without developing a high-strength suture?**

MR. FALKE: Objection, outside the scope of the notice.

A. Yes.

**Q. In the original plans to develop a high-strength suture, is it correct that they wanted to mimic Fiberwire, that DePuy Mitek wanted to mimic FiberWire?**

MR. FALKE: Outside, outside the scope of the notice, object to the form. Chuck, this is Topic 11. She's not here to talk about this. These are clearly Topic 11 questions. You can answer if you know.

MR. SABER: Well, I mean she was

# EXHIBIT 2


Revolutionizing
Orthopaedic Surgery
FiberWire®
Braided Composite Suture
Arthrex®

# Revolutionizing Orthopaedic Surgery

FiberWire suture is constructed of a multi-stranded long chain ultra-high molecular weight polyethylene core with a polyester braided jacket that gives FiberWire superior strength, soft, feel and abrasion resistance that is unequaled in orthopaedic surgery. Suture breakage during knot tying is virtually eliminated, especially critical during arthroscopic procedures. FiberWire represents a major advancement in orthopaedic surgery.

## Strength

FiberWire has greater strength than comparable size standard polyester suture. Multiple independent scientific studies document significant increases in strength to failure, stiffness, knot strength and knot slippage with much less elongation[1].

## Biocompatibility

Extensive biocompatibility, animal and clinical testing prove that FiberWire demonstrates biocompatibility characteristics equivalent to standard polyester suture. Over two years of successful clinical outcomes in over one million orthopaedic procedures substantiate excellent biocompatibility. Biocompatibility, strength and testing results are available upon request[2].

## Tie Ability and Knot Profile

Orthopaedic surgeons enthusiastically endorse FiberWire for its feel and knot tie ability. The first throw stays down, facilitating reproducible tissue repair. Sliding knots advance smoothly easing arthroscopic knot tying procedures. Superior strength allows tighter loop security during knot tying, increasing knot integrity while reducing the knot profile compared to standard polyester suture.

## Abrasion Resistance

The multi-strand long chain ultra-high molecular weight polyethylene core dramatically increases FiberWire abrasion resistance. Surgical procedures that create bone edges, tunnel edges, and articulating surface abrasion areas are appropriate indications for FiberWire. FiberWire is over five times more abrasion resistant than standard polyester suture.

## Variety

The FiberWire family has expanded to sizes 4-0 through #5 including new designs such as FiberStick and FiberSnare that provide innovative solutions to arthroscopic suture passing. TigerWire has a black spiral thread for easier arthroscopic visualization, identification, sizing and motion detection. FiberLoop is ideal for multistrand tendon repairs.

## Safety in Numbers

Trusted by leading orthopaedic surgeons worldwide since its introduction in 2002, FiberWire has contributed to successful surgical outcomes in over one million orthopaedic surgical procedures ranging from Achilles tendon repair to rotator cuff repair. Multiple scientific publications have confirmed the advantages of FiberWire in orthopaedic surgery[3,4].

*References on back...*

# FiberWire Suture Family

## FiberWire

FiberWire suture is a new generation of polyester suture with a long chain polyethylene core. FiberWire has greater strength than similar sized polyester suture with superior feel, smooth tie ability and lower knot profile. FiberWire is the ideal suture for most orthopaedic soft tissue repairs, virtually eliminating suture breakage during knot tying.

| | |
|---|---|
| #2 FiberWire, 38 inches (blue) w/Tapered Needle, 26.5 mm 1/2 circle | AR-7200 |
| #2 FiberWire, 38 inches (blue) w/Reverse Cutting Needle, 36.6 mm 1/2 circle | AR-7202 |
| #2 FiberWire Loop w/Needle for NeedlePunch, 26 inches (green), 10 mm, straight | AR-7204 |
| #2 FiberWire, 38 inches (blue) w/two Tapered Needles, 26.5 mm 1/2 circle | AR-7205 |
| #2 FiberWire, 38 inches w/Tapered Needle (blue), 36.6 mm 1/2 circle | AR-7206 |
| #2 FiberWire w/two Needles for NeedlePunch, 38 inches (blue), 10 mm, straight | AR-7207 |
| #2 FiberWire, 38 inches (1 blue, 1 white/black) w/Tapered Needle, 26.5 mm 1/2 circle | AR-7208 |
| #5 FiberWire, 38 inches (blue) | AR-7210 |
| #5 FiberWire, 38 inches (blue) w/Conventional Cutting Needle, 48 mm 1/2 circle | AR-7211 |
| 2-0 FiberWire, 18 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle | AR-7220 |
| 2-0 FiberWire, 38 inches (blue) | AR-7221 |
| 2-0 Suture Shuttle Loop for NeedlePunch, 40 mm | AR-7224 |
| 3-0 FiberWire, 18 inches (blue) w/Diamond Point Needle, 26.2 mm 3/8 circle | AR-7225 |
| 3-0 FiberWire, 18 inches (blue) w/Tapered Needle, 15 mm 3/8 circle | AR-7227-01 |
| 3-0 FiberWire, 18 inches (blue) w/Reverse Cutting Needle, 16.3 mm 3/8 circle | AR-7227-02 |
| 4-0 FiberWire, 18 inches (blue) w/Diamond Point Needle, 18.7 mm 3/8 circle | AR-7228 |
| 4-0 FiberWire, 18 inches (blue) w/Tapered Needle, 12.3 mm 3/8 circle | AR-7230-01 |
| 4-0 FiberWire, 18 inches (blue) w/Reverse Cutting Needle, 11.9 mm 3/8 circle | AR-7230-02 |
| 0 FiberWire, 38 inches (blue) w/Tapered Needle, 22.2 mm 1/2 circle | AR-7250 |
| 0 FiberWire, 38 inches (blue) w/Diamond Point Needle, 22.2 mm 1/2 circle | AR-7251 |

## TigerWire®

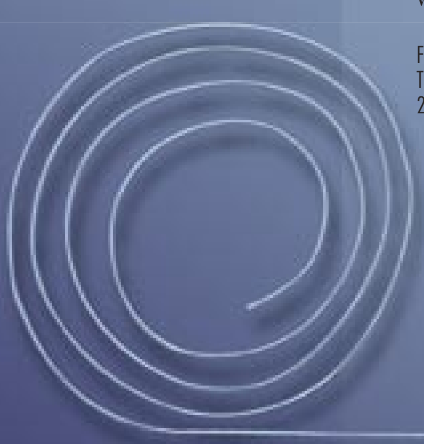
TigerWire suture utilizes the same high strength construction as FiberWire except that it contains a black marker strand in the suture weave. This strand appears as a stripe in the suture making suture identification easier during joint reconstruction and soft tissue repairs.

| | |
|---|---|
| #2 FiberWire, 38 inches (blue, white/black) | AR-7201 |
| #2 TigerWire, 38 inches (white/black) | AR-7203 |
| #2 TigerWire, 38 inches (white/black) w/two Tapered Needles,26.5 mm 1/2 circle | AR-7205T |

## FiberStick™ and TigerStick™

The stiff "waxed" end of the FiberStick and TigerStick allows convenient and easy advancement through most cannulated instruments or spinal needles, alleviating the need for a monofilament suture or wire suture shuttle. FiberStick and TigerStick come with a thin plastic tube which protects the stiffened suture end until use.

| | |
|---|---|
| FiberStick, #2 FiberWire, 50 inches (blue) one end stiffened, 12 inches | AR-7209 |
| TigerStick, #2 TigerWire, 50 inches (white/black) one end stiffened, 12 inches | AR-7209T |
| 2-0 FiberStick, 2-0 FiberWire, 50 inches (blue) one end stiffened, 12 inches | AR-7222 |



# FiberWire Suture Family

## FiberTape™

FiberTape is an ultra-high strength 2 mm width tape using a similar long chain polyethylene structure as the FiberWire suture. In addition to high demand applications like AC joint reconstruction, the broad footprint of the FiberTape is appropriate for repairs in degenerative cuff tissue where tissue pull-through may be a concern.

| | |
|---|---|
| FiberTape, 2 mm, 54 inches (blue) each end tapered to #2 FiberWire, 8 inches | AR-7237 |

## FiberLoop™

FiberLoop is a suture option for multi-strand tendon repairs. These small diameter looped FiberWire products, in 12 and 20 inch lengths, allow for strong multi-strand flexor and extensor tendon repairs while reducing tendon damage from multiple needle passes. FiberLoop is available with 17.9 mm tapered needles to prevent cutting suture while stitching.

| | |
|---|---|
| 4-0 FiberLoop, 4-0 FiberWire, 12 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle | AR-7229-12 |
| 4-0 FiberLoop, 4-0 FiberWire, 20 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle | AR-7229-20 |
| 2-0 FiberLoop, 30 inches w/Diamond Point Needle, 48 mm 1/2 circle | AR-7232-01 |
| 2-0 FiberLoop, 24 inches w/Diamond Point Needle, 26.2 mm 3/8 circle | AR-7232-02 |
| 2-0 FiberLoop, 30 inches w/Diamond Point Straight Needle, 64.8 mm | AR-7232-03 |

## FiberSnare™

FiberSnare with closed loop provides an easy one step approach to creating a FiberWire loop on the tip of the Bio-Tenodesis Driver. Instead of using a nitinol wire, insert the stiff non-looped end retrograde through the tip of the Bio-Tenodesis Screwdriver. Place the tip of the tendon or tendon graft into the FiberWire loop and cinch the other end around the suture cleat on the back end of the blue Tear Drop Handle. The FiberSnare can also be used as a suture shuttle for passage of traction sutures through bone tunnels.

| | |
|---|---|
| #2 FiberSnare, #2 FiberWire, 26 inches, (green) stiffened w/closed loop, 12 inches | AR-7209SN |

## 2-0 FiberWire Meniscus Repair Needles

2-0 FiberWire with Meniscus Needles is an excellent option for standard outside/in meniscus repair. The swedged-on FiberWire suture enables the surgeon to efficiently slide low profile knots while creating the strongest suture repair possible. The stainless steel meniscal needles easily pass through meniscal and soft tissues.

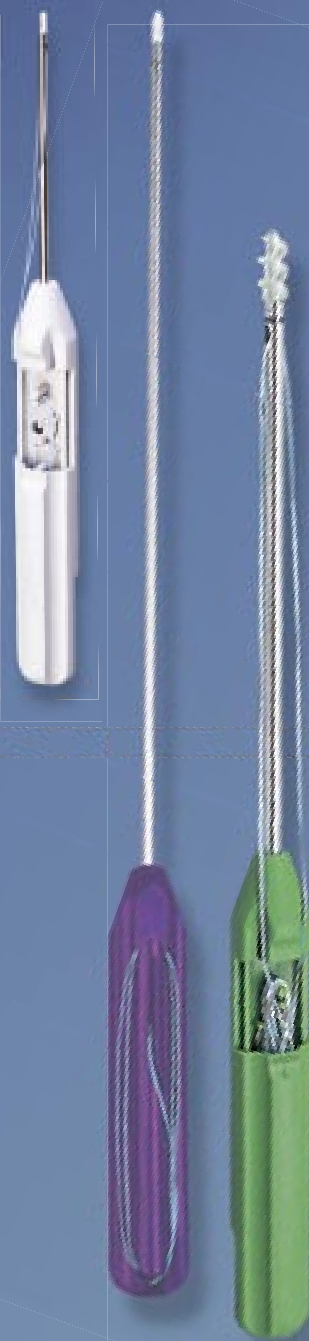
| | |
|---|---|
| #2-0 FiberWire Meniscus Repair Needles | AR-7223 |

## FiberWire Suture Kit

The FiberWire Suture Kit is available for larger complex soft tissue approximation procedures. This kit contains a total of 18 sutures including three different colored versions of #5 FiberWire for easy suture differentiation, large cutting Spring Eye Free Needles, and #2 FiberWire in one convenient package.

| | |
|---|---|
| FiberWire Suture Kit | AR-7219 |

# Suture Anchors with FiberWire



## Suture Anchors

A recent innovation that has had a significant impact on the performance of suture anchors is the availability of FiberWire suture in our suture anchors. The high strength characteristics along with significantly increased abrasion resistance gives the surgeon confidence during crucial knot tying stages where suture breakage is virtually eliminated. Each suture anchor is available with one or two strands of FiberWire and black/white striped TigerWire to facilitate suture differentiation and motion determination.

Our anchors are now available loaded with two strands of a two-toned FiberWire product, TigerTail. TigerTail, available in either blue or white, has a black stripe in one half of the suture. Anchors double loaded with TigerTail will have four visually distinct strands of FiberWire to enhance suture strand differentiation, virtually eliminating suture strand confusion.

| | |
|---|---|
| Micro Bio-SutureTak w/Needles, 2.4 mm x 5 mm, w/handled inserter and 2-0 FiberWire | AR-1320BNF |
| Mini Bio-SutureTak w/Needles, 2.4 mm x 7 mm w/2-0 FiberWire | AR-1322BNF |
| Small Bone FASTak Suture Anchor, 2.4 mm x 7.5 mm w/2-0 FiberWire | AR-1322-752SF |
| FASTak Suture Anchor, 2.4 mm x 11.7 mm w/and #2 FiberWire | AR-1322SXF |
| FASTak II Suture Anchor, 2.8 mm 11.7 mm w/#2 FiberWire | AR-1324HF |
| FASTak II Suture Anchor, 2.8 mm x 11.7 mm w/#2 FiberWire | AR-1324SF |
| Bio-FASTak Suture Anchor, 3 mm x 14 mm w/two #2 FiberWire | AR-1324BF |
| Bio-FASTak Suture Anchor, 3 mm x 14 mm w/two #2 FiberWire | AR-1324BF-2 |
| Corkscrew II Suture Anchor, 5 mm x 15.5 mm w/two #2 FiberWire (2 eyelets) (a) | AR-1902SF |
| Corkscrew Suture Anchor, 3.5 mm x 12 mm w/#2 FiberWire | AR-1915SF |
| Corkscrew Suture Anchor w/Needles, 3.5 mm x 12 mm w/two #2 FiberWire | AR-1915SNF |
| Bio-Corkscrew Suture Anchor, 3.7 mm x 17.9 mm w/two #2 FiberWire | AR-1920BF-37 |
| Corkscrew Suture Anchor w/Needles w/handled inserter and two #2 FiberWire, 5 mm x 15.5 mm | AR-1920SNF |
| Corkscrew Suture Anchor, 5 mm x 15.5 mm w/two #2 FiberWire | AR-1920SF |
| Bio-Corkscrew Suture Anchor, 5 mm x 15 mm w/two #2 TigerTail (b) | AR-1920BFT |
| Bio-Corkscrew Suture Anchor, 3.7 mm x 17.9 mm, w/two #2 TigerTail | AR-1920BFT-37 |
| Bio-Corkscrew Suture Anchor, 5 mm x 17.9 mm w/two #2 FiberWire, | AR-1920BF |
| Bio-Corkscrew Suture Anchor w/Needles, 5 mm x 17.9 mm w/two #2 FiberWire | AR-1920BNF |
| Bio-Corkscrew Suture Anchor, 5 mm x 17.9 mm w/2 mm FiberTape | AR-1920BT |
| Corkscrew Suture Anchor w/Needles, 5 mm x 15.5 mm w/two #2 FiberWire | AR-1920NSF |
| Corkscrew Suture Anchor, 5 mm x 15.5 mm w/two #2 TigerTail | AR-1920SFT |
| Bio-Corkscrew Suture Anchor w/NeedlePunch Needles, 5 mm x 17.9 mm w/two #2 FiberWire | AR-1920BNP |
| Bio-Corkscrew Suture Anchor, 6.5 mm x 17.9 mm w/two #2 FiberWire | AR-1925BF |
| Bio-Corkscrew Suture Anchor w/Needles, 6.5 mm x 17.9 mm w/two #2 FiberWire | AR-1925BNF |
| Corkscrew Suture Anchor, 6.5 mm x 15.5 mm w/two #2 FiberWire | AR-1925SF |
| Bio-Corkscrew FT Suture Anchor, 5.5 mm x 15 mm w/two #2 FiberWire (d) | AR-1927BF |
| Bio-Corkscrew FT Suture Anchor, 5.5 mm x 15 mm, w/two #2 TigerTail | AR-1927BFT |
| Bio-Corkscrew FT Suture Anchor w/Needles, 5.5 mm x 15 mm w/two #2 FiberWire | AR-1927BNF |
| Bio-Corkscrew FT w/NeedlePunch Needles, 5.5 mm x 15 mm w/two #2 FiberWire | AR-1927BNP |
| Bio-Corkscrew FT w/ four NeedlePunch Needles, 5.5 mm x 15 mm w/two #2 FiberWire *(for mini open procedures only)* | AR-1927BNP4 |
| Corkscrew FT II Suture Anchor w/NeedlePunch Needles, 5.5 mm x 14 mm w/two #2 FiberWire | AR-1928NP-2 |
| Corkscrew FT II Suture Anchor, 5.5 mm x 16 mm w/two #2 FiberWire | AR-1928SF |
| Corkscrew FT II Suture Anchor, 5.5 mm x 16 mm w/two #2 TigerTail | AR-1928SFT-2 |
| Corkscrew FT II Suture Anchor w/two #2 FiberWire, 5.5 mm x 14 mm (c) | AR-1928SF-2 |
| Corkscrew FT II Suture Anchor w/Needles, w/two #2 FiberWire with 26 mm 1/2 circle needles, 5.5 mm x 14 mm | AR-1928SNF-2 |
| PEEK Corkscrew FT II Suture Anchor, 5.5 mm x 14 mm w/two #2 FiberWire | AR-1928PSF-2 |
| Bio-SutureTak Suture Anchor w/#2 FiberWire, 3 mm x 14 mm (e) | AR-1934BF |
| Bio-SutureTak Suture Anchor w/two #2 FiberWire, 3 mm x 14 mm | AR-1934BF-2 |
| Bio-SutureTak Suture Anchor, 3 mm x 14 mm w/#2 TigerTail | AR-1934BFT |
| Bio-SutureTak Suture Anchor, 3.7 mm x 14 mm w/#2 FiberWire | AR-1934BLF |
| Bio-SutureTak Suture Anchor, 3.7 mm x 16 mm w/#2 TigerTail | AR-1934BLFT |
| PEEK SutureTak Suture Anchor, 3 mm x 12 mm w/#2 FiberWire | AR-1934PS |


a


b


c


d


e

# FiberWire Accessories

## Suture Cutters

The Suture Cutters were designed to facilitate arthroscopic suture cutting with specially designed cutting jaws, with and without visual control.

The Suture Cutter's precision jaws prevent knot cutting by leaving a length of reproducible suture tail, 3 mm for the 4.2 mm outer diameter cutter and 1 mm for the 2.75 mm outer diameter cutters, without direct visual control. These cutters have a special locking device to prevent premature suture cutting. The blunt tip of the cutter is excellent for knot pushing.

The Open Ended Suture Cutter was designed to speed up the suture cutting process. This cutter allows for quick and efficient suture tail cutting under direct visual control through the same or alternate cannula or portal. The notch on the side of the cutter tip automatically guides the suture tails into the front cutting slot for an accurate cut from any angle.

All Suture Cutters are recommended for cutting FiberWire.

| | |
|---|---|
| Suture Cutter, 4.2 mm, straight | AR-12250 |
| 2-0 Suture Cutter, 2.75 mm, straight | AR-11790 |
| 2-0 Suture Cutter, 2.75 mm, 15° up curve | AR-11791 |
| Suture Cutter, Open Ended, Left Notch | AR-11794L |

## FiberWire Scissor

The FiberWire Scissor was designed to cut any size or style suture, especially FiberWire, in open surgical cases where an arthroscopic suture cutter is not necessary. With its specially designed cutting edges, it can cut FiberWire cleanly and effortlessly without frayed edges. The color coded handle facilitates instrument differentiation in large instrument packs.

| | |
|---|---|
| FiberWire Scissor | AR-11796 |
| FiberWire Scissor, small | AR-11797 |

## FingerShield™

The FingerShield is a woven white polyester sleeve with an embedded radiopaque blue marker designed to reduce pressure induced lacerations to the digits of the hand caused by repetitive knot tying during surgical cases. They slip right over sterile gloves when needed. The tips are left open to allow pinch grasp of suture strands while still protecting the IP joint area of each digit. The soft, finger conforming weave will stand up to repetitive hand tying during a case without constraining the fingers. Suture slides over the FingerShield smoothly and effortlessly. There are two FingerShields per sterile pack.

| | |
|---|---|
| FingerShield, 2/pk | AR-7199 |

## FiberWire Tensioner

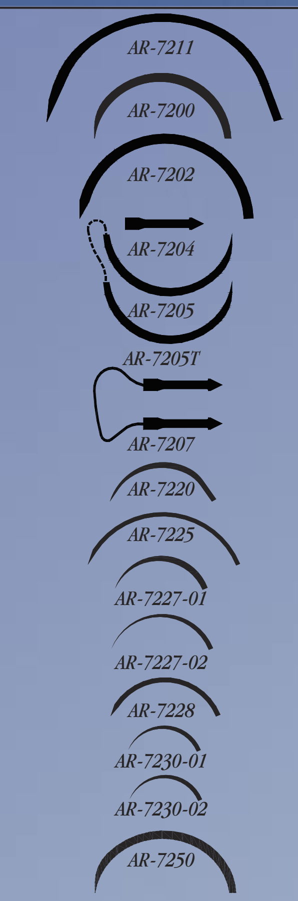
The FiberWire Tensioner provides controlled tensioning of FiberWire loops during knot tying when reapproximating soft tissue. The blunt tip keeps the knot in place while the tensioning wheel and spring mechanism gently tension the loop to tighten the repair. It is appropriate for use in conjunction with #5 FiberWire.

| | |
|---|---|
| FiberWire Tensioner | AR-1929 |
| Suture Passing Wire | AR-1255-18 |
| #5 FiberWire, 38 inches (blue) | AR-7210 |

# Arthrex FiberWire® Reference Chart

Detach and Hang

## FiberWire

| Suture Size | Suture Length | Description | Needle Dimensions | Needle Reference | Recommended Uses | Supplied | Cat Number | Box Color | Actual Size of Needles |
|---|---|---|---|---|---|---|---|---|---|
| #5 (7 metric) | 38 inches | 1 strand (blue) | | | Use with FiberWire Tensioner for Tendon, Ligament or Soft Tissue Repair, AC Joint Repair | 12/box | AR-7210 | |  |
| #5 (7 metric) | 38 inches | 1 strand (blue) with Conventional Cutting Needle | 48 mm 1/2 circle | CCS-1 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7211 | | |
| #2 (5 metric) | 38 inches | 1 strand (blue) with Tapered Needle | 26.5 mm 1/2 circle | T-5 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7200 | | |
| #2 (5 metric) | 38 inches | 2 strands (blue, white/black) | | | Reload suture anchors, use with Viper | 12/box | AR-7201 | | |
| #2 (5 metric) | 38 inches | 1 strand (blue) w/Reverse Cutting Needle | 36.6 mm 1/2 circle | C-13 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7202 | | |
| #2 (5 metric) | 38 inches | 1 strand (white/black) TigerWire | | | Reload Suture Anchors | 12/box | AR-7203 | | |
| #2 (5 metric) | 26 inches | 1 strand (blue) w/closed Loop and NeedlePunch Needles | 10 mm | | Rotator Cuff Repair | 10/box | AR-7204 | | |
| #2 (5 metric) | 38 inches | 1 strand (blue) w/two Tapered Needles | 26.5 mm 1/2 circle | T-5 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7205 | | |
| #2 (5 metric) | 38 inches | 1 strand (blue) w/Tapered Needle | 36.6 mm 1/2 circle | T-5 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7206 | | |
| #2 (5 metric) | 38 inches | 1 strand (white/black) TigerWire w/two Tapered Needles | 26.5 mm 1/2 circle | T-5 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7205T | | |
| #2 (5 metric) | 38 inches | 1 strand (blue) w/two NeedlePunch Needles | 10 mm | | Rotator Cuff Repair | 10/box | AR-7207 | | |
| #2 (5 metric) | 38 inches | 2 strands (blue, white/black) w/Tapered Needle | 26.5 mm 1/2 circle | T-5 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7208 | | |
| 2-0 (3 metric) | 18 inches | 1 strand (blue) w/Tapered Needle | 17.9 mm 3/8 circle | T-13 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7220 | | |
| 2-0 (3 metric) | 38 inches | 1 strand (blue) | | | Meniscal Repair | 12/box | AR-7221 | | |
| 3-0 (2 metric) | 18 inches | 1 strand (blue) w/Diamond Point Needle | 26.2 mm 3/8 circle | DE-14 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7225 | | |
| 3-0 (2 metric) | 18 inches | 1 strand (blue) w/Tapered Needle | 15 mm 3/8 circle | T-43 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7227-01 | | |
| 3-0 (2 metric) | 18 inches | 1 strand (blue) w/Reverse Cutting Needle | 16.3 mm 3/8 circle | C-22 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7227-02 | | |
| 4-0 (1.5 metric) | 18 inches | 1 strand (blue) w/Diamond Point Needle | 18.7 mm 3/8 circle | DE-10 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7228 | | |
| 4-0 (1.5 metric) | 18 inches | 1 strand (blue) w/Tapered Needle | 12.3 mm 3/8 circle | T-12 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7230-01 | | |
| 4-0 (1.5 metric) | 18 inches | 1 strand (blue) w/Reverse Cutting Needle | 11.9 mm 3/8 circle | C-17 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7230-02 | | |
| 0 (1.5 metric) | 38 inches | 1 strand (blue) w/Tapered Needle | 22.2 mm 1/2 circle | T-4 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7250 | | |
| 0 (1.5 metric) | 38 inches | 1 strand (blue) w/Diamond Point Needle | 22.2 mm 1/2 circle | D-10 | Tendon, Ligament or Soft Tissue Repair | 12/box | AR-7251 | | |



## FiberStick

| Suture Size | Suture Length | Description | Needle Dimensions | Needle Reference | Recommended Uses | Supplied | Cat Number | Box Color | Actual Size of Needles |
|---|---|---|---|---|---|---|---|---|---|
| #2 (5 metric) | 50 inches | 1 strand (blue) one end stiffened, 12 inches | | | Rotator Cuff Repair, Glenoid Labrum Repair and Capsular Plication | 5/box | AR-7209 | | |
| #2 (5 metric) | 50 inches | 1 strand (black/white) one end stiffened, 12 inches | | | Rotator Cuff Repair, Glenoid Labrum Repair and Capsular Plication | 5/box | AR-7209T | | |
| 2-0 (3 metric) | 50 inches | 1 strand (blue) one end stiffened, 12 inches | | | Rotator Cuff Repair, Glenoid Labrum Repair, Capsular Plication, TFCC Repair and Meniscal Repair | 5/box | AR-7222 | | |

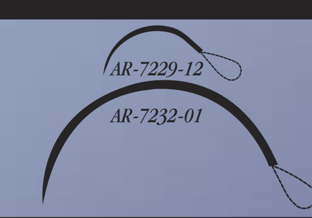
## FiberTape

| Suture Size | Suture Length | Description | Needle Dimensions | Needle Reference | Recommended Uses | Supplied | Cat Number | Box Color | Actual Size of Needles |
|---|---|---|---|---|---|---|---|---|---|
| | 54 inches | 2 mm (blue) each end tapered to #2 FiberWire, 8 inches | | | AC Joint Repair | 6/box | AR-7237 | | |

## FiberSnare

| Suture Size | Suture Length | Description | Needle Dimensions | Needle Reference | Recommended Uses | Supplied | Cat Number | Box Color | Actual Size of Needles |
|---|---|---|---|---|---|---|---|---|---|
| #2 (5 metric) | 26 inches | 1 strand (green) stiffened w/closed loop, 12 inches | | | Use with Bio-Tenodesis Driver for Tendon Snare | 12/box | AR-7209SN | | |

## FiberLoop

| Suture Size | Suture Length | Description | Needle Dimensions | Needle Reference | Recommended Uses | Supplied | Cat Number | Box Color | Actual Size of Needles |
|---|---|---|---|---|---|---|---|---|---|
| 4-0 (1.5 metric) | 12 inches | 1 strand (blue) w/Tapered Needle | 17.9 mm 3/8 circle | T-13 | Multi-strand Tendon Repairs | 12/box | AR-7229-12 | |  |
| 4-0 (1.5 metric) | 20 inches | 1 strand (blue) w/Tapered Needle | 17.9 mm 3/8 circle | T-13 | Multi-strand Tendon Repairs | 12/box | AR-7229-20 | | |
| 2-0 (1.5 metric) | 30 inches | 1 strand (blue) w/Diamond Point Needle | 48 mm 1/2 circle | DE-14 | Multi-strand Tendon Repairs | 12/box | AR-7232-01 | | |
| 2-0 (1.5 metric) | 24 inches | 1 strand (blue) w/Diamond Point Needle | 26.2 mm 3/8 circle | D-17 | Multi-strand Tendon Repairs | 12/box | AR-7232-02 | | |
| 2-0 (1.5 metric) | 30 inches | 1 strand (blue) w/Diamond Point Straight Needle | 64.8 mm | SD-2 | Multi-strand Tendon Repairs | 12/box | AR-7232-03 | | |

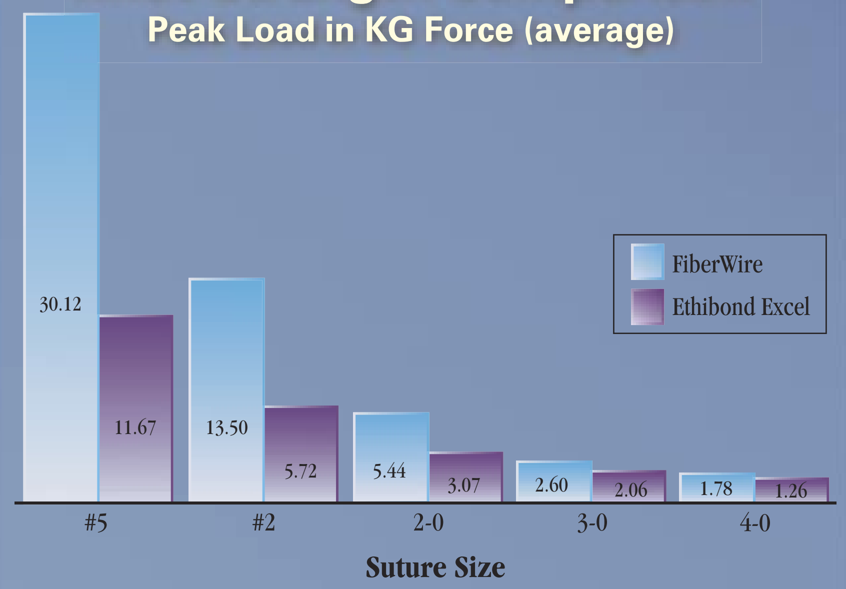


## FiberWire Suture Kit

| Suture Size | Suture Length | Description | Needle Dimensions | Needle Reference | Recommended Uses | Supplied | Cat Number | Box Color | Actual Size of Needles |
|---|---|---|---|---|---|---|---|---|---|
| #5 (7 metric) | 38 inches | 4 strands (blue), 4 strands (white) and 4 strands (green) | 60 mm 3/8 circle, 80 mm 1/2 circle | | Soft Tissue Fixation | 1/box | AR-7219 | | |
| #2 (5 metric) | 38 inches | 6 strands (blue) w/Tapered needle | 26.5 mm 1/2 circle | T-5 | Soft Tissue Reconstruction | | | | |

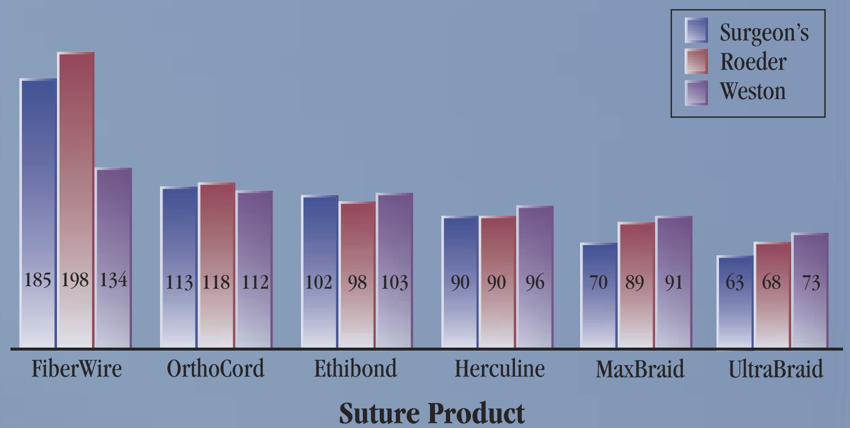
## Knot Strength Comparison

**Peak Load in KG Force (average)**




## Knot Security

**Average Force (N) Causing 3 mm Loop Displacement - #2 Size Suture**




* *Data on file*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U.S. PATENT NO. 5,964,783; 6,117,162; 6,214,031; 6,511,499; 6,652,563 and 6,716,234

# EXHIBIT 3

EXTENDED–CHAIN FIBER

# SPECTRA®
# EXTENDED CHAIN POLYETHYLENE FIBERS



Allied Fibers

AlliedSignal Technologies

# SPECTRA®

## HIGH PERFORMANCE FIBERS FOR REINFORCED COMPOSITES

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# SPECTRA® EXTENDED CHAIN POLYETHYLENE FIBERS

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## 1. HISTORY

Extended Chain Polyethylene (ECPE) fibers are the most recent entrants in the high performance fibers field. SPECTRA® ECPE, the first commercially available ECPE fiber, was introduced in February 1985. They are the first in a family of extended chain polymers manufactured by Allied-Signal Corporation.

SPECTRA® ECPE fibers are, pound for pound, the highest modulus and strongest fibers ever made. This is a noteworthy achievement on two counts. First, because industry had relegated it to the status of a general purpose commodity polymer, polyethylene was not considered as a specialized high performance product. Second, the discovery was not made in a large industrial polymer laboratory, but from fundamental work by researchers in several leading universities. Although the work was supported by industry, the immediate outcome was not foreseen as a commercial entity. It is, however, an example of industry recognizing the value of revolutionary findings and exploiting the promise of technology. The result was the transformation of a commodity type polyethylene (PE) plastic into a high performance fiber.

Today, ECPE fibers are being utilized as a reinforcement in areas that, five years ago, were not accessible to any organic fiber. Applications such as ballistic armor, impact shields, and radar domes are being developed to take advantage of the unique properties of ECPE.

## 2. CHEMISTRY

SPECTRA® fibers are made from ultra-high molecular weight polyethylene (UHMPE). In contrast to aramids, PE is a flexible molecule which normally crystallizes by folding back on itself. As a consequence, P.E. fibers made by conventional technology do not possess outstanding physical properties. ECPE fibers, on the other hand, are manufactured by a process where most of the molecules are fully extended and oriented in the fiber direction, resulting in a dramatic increase in physical properties. A simplistic view of the structure on a molecular scale could be described as a bundle of rods, with occasional entangled points that tie the structure together. Conventional PE, on the other hand, contains a number of chain folds of short length which do not make a contribution to strength.

The key structural parameters that distinguish ECPE fibers from conventional melt spun materials are further illustrated in Figure 1. The molecular weight of UHMPE is generally 1 to 5 million, whereas conventional P.E. fibers are typically 50,000 to several hundred thousand. SPECTRA® fibers also exhibit a very high degree of crystalline orientation (95-99%), and crystalline content (60-85%).

## 3. MANUFACTURING

Two general routes can be used to achieve high-modulus PE fibers. The first is by extrusion, such as melt extrusion or by solid-state extrusion, utilizing lower molecular weight PE polymer and specialized drawing techniques. These processes lead to a fiber with high modulus, but relatively low strength and high creep. The second route involves solution spinning, where very high molecular weight PE can be utilized. With this process modification, a fiber with both high modulus and high strength is produced.

The solution spinning process for a generalized extended chain fiber begins with a polymer of approximately 1-5 million molecular weight, which is dissolved in a suitable solvent. The solution serves to disentangle the polymer chains-a key step in achieving an extended chain polymer structure. The solution is fairly dilute but viscous enough to be spun using conventional melt spinning equipment. The cooling of the extrudate leads to the formation of a fiber which can be continuously dried to remove solvent or later extracted by an appropriate solvent. The fibers are generally post drawn prior to final packaging.

Unlike most high performance processes, the solution spinning process is unusually flexible, providing an almost infinite number of process and product variations. Fiber strengths from 375 KSI to 560 KSI and tensile moduli of 15 MSI to 30 MSI have been achieved on a research scale by various companies worldwide. As the solution spinning process is modified, a higher tenacity (stronger) and more thermally stable yarn is produced. Circumstantial evidence (such as increased density, heat of fusion and x-ray orientation pattern) suggests that the increased strength and stability are caused by higher degrees of molecular orientation.

# 4. APPLICATIONS

## 4.1 Fiber Properties

The comparative strengths of ECPE fibers versus other high performance fibers are summarized in Table 1. SPECTRA® 900, produced by Allied-Signal, will be used to illustrate the general properties of ECPE. SPECTRA® 1000 fibers are more stabilized, and exhibit a higher strength and modulus. In engineering terms, the tensile properties of ECPE are similar to many high performance fibers. However, because of the low density of PE (approximately 2/3 that of high modulus aramid and half that of high modulus carbon fiber), SPECTRA® fibers have extraordinarily high specific strengths and specific moduli. Pound for pound, the strength of SPECTRA® fiber is at least 35% greater than high modulus aramid or S-Glass, and about twice that of conventional high modulus carbon fiber. When comparing high performance fibers, it is often informative to employ a graphical illustration of Table 1. A two-dimensional plot of specific strength versus specific modulus for currently available fibers is given in Figure 2, again emphasizing the superior properties of SPECTRA®.

Polyethylene is also known as a system where traditional binders and wetting agents have proven to be ineffective in improving adhesion levels. ECPE fibers have shown that this characteristic is actually advantageous in specific areas. For instance, ballistic performance is inversely related to the degree of adhesion between the fiber and the resin matrix. For applications which need higher levels of adhesion and wetout, extensive research has been performed on SPECTRA® fibers. It has been found that by submitting the fiber to specific surface treatments, such as corona discharge or plasma treatments, the adhesion of the fiber to various resins is dramatically increased (see Table 2).

The main application areas being explored and commercialized today for SPECTRA® fibers are divided into two main thrusts: traditional fiber applications such as sailcloth, marine ropes, cables, sewing thread, nettings, and protective clothing; and high tech composite applications, such as ballistics, impact shields, medical implants, radomes, pressure vessels, boat hulls, sports equipment, and concrete reinforcement.

## 4.2 Sailcloth

World class competition of high performance sail boats (such as the Americas Cup) has become more competitive, forcing the sail industry to experiment with new materials. A winning sailcloth must possess high strength, high modulus, light weight and minimal distortion during the sailing season. Of the fiber physical properties, none are more critical than low creep and resistance to sea water and cleaning agents. Because of its superior strength-to-weight ratio and low creep response, SPECTRA® 1000 fibers are ideally suited for high performance yachting sails. Further, PE fibers are resistant to sea water and to typical cleaning solutions used in the boating industry, such as clorox (see Figure 3).

The creep behavior of SPECTRA® extended-chain fibers under typical laboratory test loadings of 3-4 gram/denier is illustrated in Figure 4. These creep levels are substantially below those encountered with conventional PE or the specialized high modulus fibers from melt spinning. At this loading, which includes the initial elastic loading component, the creep level of SPECTRA® 1000 is comparable to that of a high modulus aramid. The elastic load component is included in these results on a practical basis since it is an integral part of the sail cloth design.

## 4.3 Marine Ropes

High strength, light weight, low moisture absorption and excellent abrasion resistance all make ECPE a natural candidate for marine rope. Three parameters of SPECTRA® 900 rope (diameter, weight per length, and strength) are illustrated in Table 3. Since aramid fibers are the accepted standard in the high performance rope industry, aramids will be used here to provide a yardstick by which the ECPE fibers can be measured. SPECTRA® 900 braid is 12% smaller, 10% stronger and 52% lighter than the aramid product.

The important considerations in marine rope applications are load, cycling and abrasion resistance. The response of a SPECTRA® 900 rope to load cycling was measured by testing on a sheave device. The rope was repeatedly loaded to 4000 lb until it broke. In this type of test, a 12 strand ECPE braid withstood approximately eight times the number of cycles that led to failure in the control 12 strand aramid braid (Table 4). Abrasion resistance was measured by cycling the rope over an oscillating bar. In this test, 0.5 inch diameter ECPE braided rope withstood eight times the abuse of a similar aramid rope (Table 4).

## 4.4 Cut Resistant Gloves And Protective Clothing

The specially toughened and dimensionally stabilized SPECTRA® 1000 yarn has made a revolutionary new line of cut-resistant products. This technology offers a previously unattainable level of protection from cut and abrasion without sacrificing comfort and launderability. Spectra® fibers are being used in the form of cut resistant gloves, arm guards and chaps. Specific industries involved include: meat packing, commercial fishing, poultry processing, sheet metal work, glass cutting, and power tool use. The inert chemical nature combines with cut protection for non-permeable over-gloves in surgical, dental, laboratory testing, and police emergency response applications.

## 4.5 Ballistic Protection

ECPE's high strength and modulus and low specific gravity offer higher ballistic protection at a lower areal density than is possible with currently used materials. It can be used in flexible and rigid armor.

Flexible armor is manufactured by joining multiple layers of fabric into the desired shape. The style of the fabric and number of layers will determine the

ballistic resistance that the armor will provide. Typical V50 ballistic limits of plain weave SPECTRA® fabrics of different denier yarns are plotted as functions of areal density in Figure 5. Applications include protective vests for military personnel and civilian security forces as well as ballistic blankets. These blankets can be applied to ceramic and metallic armor as a front spall shield and as a rear spall suppressor. They can also be used to fabricate ballistic protective shelters.

Traditional rigid armor can also be made by utilizing woven ECPE fiber in either thermoset or thermoplastic matrices. These rigid systems exhibit high ballistic protection due to the fiber strength and modulus in combination with its low specific gravity; that is, maximum ballistic protection is achieved with minimum weight. This increased protection is illustrated in Figure 6, which compares V50 values for SPECTRA® fiber and aramid composites against a 22 caliber fragment simulator.

The ECPE fiber ballistic systems can be contoured or formed into armored plates, helicopter seats, Army or police helmets, and many other product forms. It is important for these systems to maintain their ballistic protection under a wide range of environmental conditions. For example, Figure 7 illustrates the superior performance of SPECTRA® fiber armor, even at temperatures as high as 225°F. This performance, along with the low moisture absorption, chemical inertness, and low weight characteristics make ECPE fibers a natural in the ballistic area.

### 4.6 Composites

ECPE fibers are recent entrants into the high performance composite industry. Their high strength and high modulus were the main attributes which attracted the composite industry, leading to the investigation of potential applications.

SPECTRA® fibers have been used with a wide variety of resin systems, including: epoxies, polyesters, vinylesters, silicones, urethanes and polyethylene. The choice of resin is most often dictated by the end use application and requirements. Epoxy and IPN resins provide the highest mechanical properties currently reported; epoxies being used most often by the composites industry, and IPNs gaining importance in RIM/RTM processes. Vinylester and urethanes, on the other hand, offer the greatest impact and ballistic properties at the expense of mechanical strength. Polyester is intermediate to the two groups, and is most often used in the radome industry for its electrical properties. ECPE fibers can be processed essentially the same as aramid, graphite, and glass. Hand layup, matched mold, pressure, and vacuum molding of fabric prepregs are most often used; however, filament winding and pultrusion are also common with continuous filament.

SPECTRA® fibers can be found in various forms; roving, fabric, continuous mat, and even chopped fiber. Composite applications where high strength (i.e. tensile, flexural, or short beam shear) are needed require special fiber treatments to enhance the fiber to matrix adhesion. Allied-Signal, Inc. has developed proprietary treatments for their SPECTRA® fibers to increase the adhesion level and composite properties.

#### 4.6.1 Composite Applications

SPECTRA® fiber reinforced materials are being developed and used widely in ballistics, radar protective domes, aerospace, sport equipment, and industrial applications. Some of these areas utilize the fiber in hybrid form, i.e. in combination with S-2 Glass, Graphite, Aramid, and/or Quartz.

Ballistics are so far the dominant market segment. Components include helmets, helicopter seats, automotive and aircraft armor, bullet proof radomes, and other industrial structures.

Radar protective domes (radomes) is another market utilizing ECPE fibers. Because of the excellent electrical properties of polyethylene, SPECTRA® composite systems act as a shield that is virtually transparent to microwave signals, even in high frequency regions. Hybridization with quartz or glass fiber are also attractive from the structural, cost, and performance point of view.

The major sport equipment applications to date have been canoes, kayaks, snow and water skis. Numerous other sport applications are under development, including: bicycles, golf clubs, ski poles, and tennis rackets. Further growth is expected in formula race car bodies.

The industrial market is taking advantage of SPECTRA® fibers in areas where increased strength, impact resistance, non-catastrophic failure, lightweight, or corrosion resistance are required. The corrosion resistance has led the composite industry to investigate applications where parts are exposed to a wide variety of chemical elements. Until now, standard high performance fibers could not function under such adverse conditions.

## 5. PROPERTIES OF COMPOSITES

The various fiber characteristics discussed so far can be translated into several unique composite properties. The following discussion will be organized into the following categories:

1. Ballistic
2. Impact
3. Electrical
4. Structural

### 5.1 Ballistic Performance

The ballistic performance of SPECTRA® fabrics has been presented as a function of areal density and fiber denier in the ballistic protection section. The excellent protection of SPECTRA® fabrics can be translated into hard armor composites. For example, ballistic protection against .22, .30, and .50 caliber threats is summarized in Figure 8. Looking back to Figure 6, one can see the advantage of SPECTRA® composites over similar composites reinforced with aramid fibers for fragmentation protection.

Handgun projectiles present a different type of threat, and again, SPECTRA® composites face up to the challenge with reduced weight and increased protection over aramid composites. The resistance to handgun ammunition of SPECTRA® and aramid composites are compared in Table 5. In every case, the SPECTRA® composites demonstrate lower areal density and/or increased protection.

## 5.2 Impact Resistance

Energy dissipation is one of the most outstanding features of ECPE. For instance, a comparison of fabric composites of SPECTRA®, Glass, Kevlar and Graphite under impact conditions is presented in Table 6. The SPECTRA® composite panels had significantly better impact properties, and were not "through penetrated" as the other panels were. Another unique behavior of SPECTRA® composites under impact loading is highlighted by repetitive impact studies. Figure 9 presents repetitive impact data for a similar SPECTRA® composite panel. Toughness gradually increases after each successive impact, working to extend the actual part life.

Drop weight instrumented impact tests were also performed on honeycomb sandwich composites. Again, the peak forces resisted by the SPECTRA® plates were consistently higher than similar aramid plates (Table 7). The peak impact force, total impact energy, and energy absorbed to peak force increase with the increase in face sheet thickness, from 1 to 3 plies. Resistance to hailstorm erosion is a practical example of the advantages that can be gained from the tremendous impact resistance offered by SPECTRA® honeycomb sandwich composites. A comparison with other reinforcements in a simulated hailstorm test is shown in Figure 10.

With the new surface treatments developed to enhance the fiber-resin interface adhesion, direct effects on the impact performance can be seen in Table 6. It should be noted that although the impact properties have decreased, the impact resistance of treated SPECTRA® composites is still five times that of glass or aramid, with a significant increase in physical properties.

## 5.3 Electrical Properties

Radar protective covers (radomes) are gaining an increasingly important role in today's radar systems. The most important attribute for a radome to possess is to be as close to "invisible" or "transparent" to the signal as possible. Because of the low dielectric constant and loss tangent of polyethylene, (see Table 8) SPECTRA® fiber composite systems can fulfill this requirement better than any other high performance fiber. The SPECTRA® composite low dielectric constant (2.3-2.5) has been shown to hold in the high frequency ranges, even up to the millimetric band. The superior electrical properties of ECPE fibers can be utilized in single fiber systems, or can be used to improve the properties of glass radomes via hybridization. A dielectric constant of 2.9 has been obtained with a SPECTRA®/Glass (25/75) hybrid system.

The advantages of low dielectric and low loss UHSPE fibers in radar systems can be demonstrated by observing the effect of the radome on the transmission ratio. The transmitted signal of a typical SPECTRA® radome matrix is compared with a glass radome at various ratios of wall thickness to wavelength in Figure 11. The SPECTRA® radome causes much less distortion of the signal. This advantage is even more pronounced in Type A honeycomb sandwich panels (Figure 12). By causing less signal reflection and absorbence, SPECTRA® fiber composite systems are uniquely suited to radome applications.

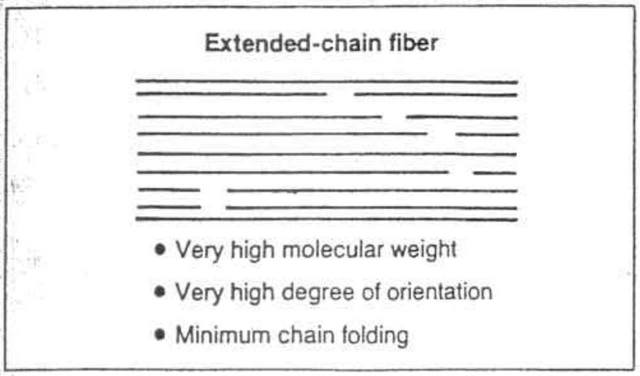
Other possible electrical applications for ECPE fibers and their reinforced composites are electrical shelters, x-ray tables, optical cables, and other structures where high strength non-conductive characteristics are needed.

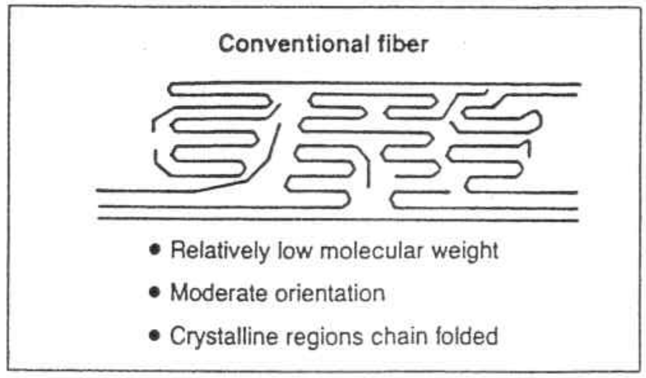
## 5.4 Structural Properties

Static test results for SPECTRA® 900 and SPECTRA® 1000 unidirectional composites are summarized in Table 9. All test samples were cut from unidirectional prepregs of corona treated ECPE fiber with Shell Epon 825 epoxy resin and Mellamine 5260 cycloaliphatic diamine curing agent. The strength and modulus of SPECTRA® 1000 are higher than the SPECTRA® 900 composites, due to the improved strength of the SPECTRA® 1000 fiber. Further improvements in composite properties can be achieved by applying the plasma surface treatment to the fibers. This treatment increases the interfacial bonding, which translates into even higher composite structural properties, as described previously in Table 2.

The continuing research in improving the ECPE fiber-matrix compatibility along with hybridization with other high performance fibers open a wide new area in composite properties. These developments are currently being explored by scientists at Allied-Signal.

**Figure 1.** *Fiber Morphology.*



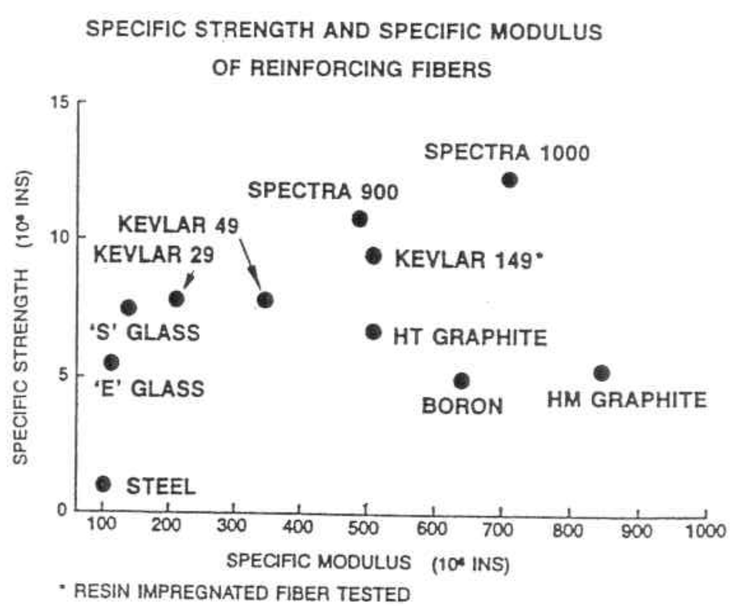




## TABLE 1
## HIGH PERFORMANCE FIBER PROPERTIES

| | UHSPE SPECTRA 1000 | ARAMID HM | ARAMID UHM* | S-Glass | Graphite HM |
|---|---|---|---|---|---|
| Property | | | | | |
| Density | 0.97 | 1.44 | 1.47 | 2.49 | 1.86 |
| Elongation, % | 2.7 | 2.5 | 1.5 | 5.4 | 0.6 |
| Tensile Strength, $10^3$ psi | 435 | 400 | 500 | 665 | 375 |
| Specific Strength, $10^6$ in | 12.4 | 7.8 | 9.5 | 7.4 | 5.4 |
| Tensile Modulus, $10^6$ psi | 25 | 19 | 25 | 13 | 57 |
| Specific Modulus, $10^6$ in | 714 | 365 | 480 | 140 | 850 |

* Kevlar 149 — Epoxy Impregnated Strand

**Figure 2.** *Comparative tensile properties of various reinforcing fibers.*



## TABLE 2
## UHSPE FIBER ADHESION IMPROVEMENTS

**Fiber:** SPECTRA® 900

**Resin:** Epoxy

**Fiber Loading:** 60%

| | | Unidirectional | | | Fabric (Style 903) | | |
|---|---|---|---|---|---|---|---|
| Date | Treatment | SBS (KSI) | Flex Str (KSI) | Flex Mod (MSI) | SBS (KSI) | Flex Str (KSI) | Flex Mod (MSI) |
| 10/85* | TN[1] | 1.16 | 21.2 | 1.2 | 0.87 | 5.7 | 0.44 |
| 10/86 | CT[2] | 2.61 | 27.6 | 2.6 | 1.4 | 10.3 | 1.0 |
| 10/87 | TP[3] | 4.50 | 33.9 | 4.5 | 2.2 | 21.0 | 2.9 |

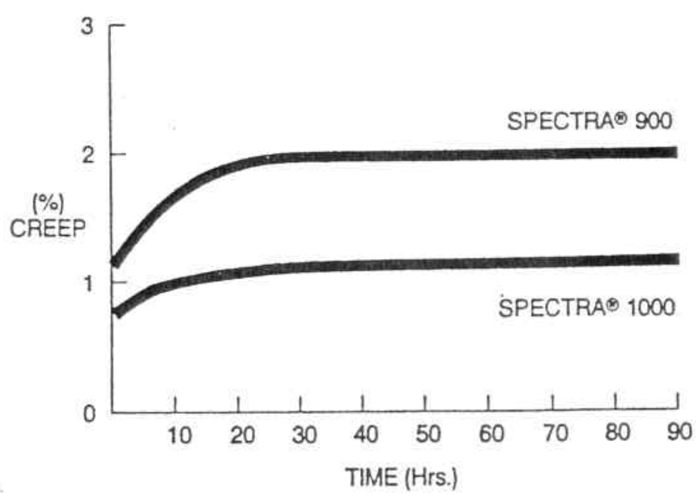
* Market Introduction [1] No Treatment [2] Corona Treatment [3] Plasma Treatment

**Figure 3.** *Chemical resistance.*

| Agent | % Strength Retention After 6 Months Immersion: SPECTRA 900 | Aramid |
|---|---|---|
| Sea Water | 100 | 100 |
| 10% Detergent solution | 100 | 100 |
| Hydraulic fluid | 100 | 100 |
| Kerosene | 100 | 100 |
| Gasoline | 100 | 93 |
| Toluene | 100 | 72 |
| Perchlorethylene | 100 | 75 |
| Glacial acetic acid | 100 | 82 |
| 1M Hydrochloric acid | 100 | 40 |
| 5M Sodium hydroxide | 100 | 42 |
| Ammonium hydroxide (29%) | 100 | 70 |
| Hypophosphite solution (10%) | 100 | 79 |
| Clorox® | 91 | 0 |

Immersed in various chemical substances for a period of 6 months, SPECTRA fibers retained their original strength.

**Figure 4.** *Creep at 10% load (room temperature).*



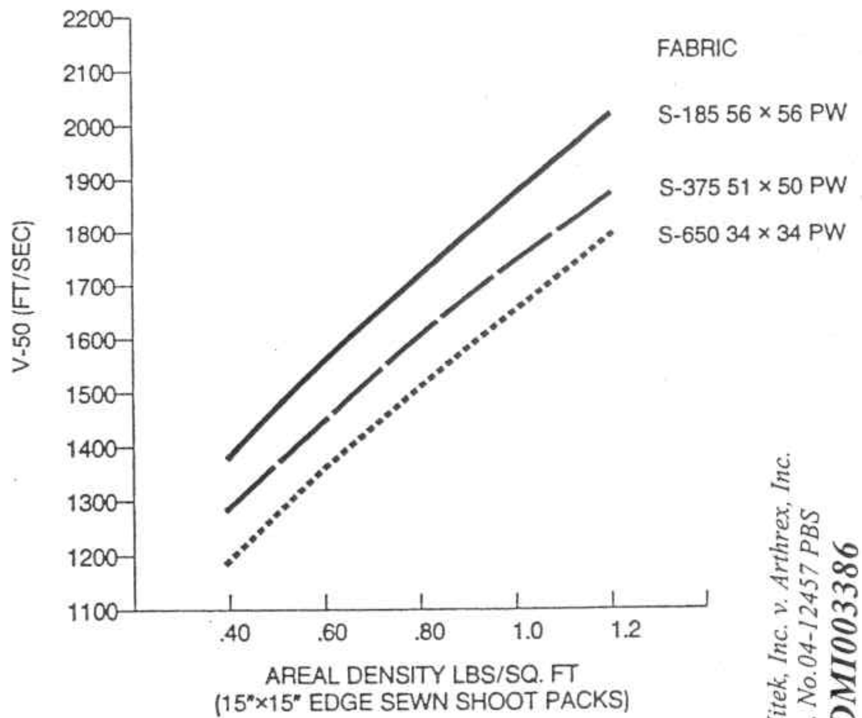
## TABLE 3
## COMPARATIVE PROPERTIES OF 16-STRAND ROPE

| Property | SPECTRA® 900 | Aramid |
|---|---|---|
| Diameter (In) | 0.088 | 0.10 |
| Wt/100 Ft (Lb) | 0.153 | 0.32 |
| Tensile Strength (Lb) | 1465 | 1334 |

## TABLE 4
## CYCLE LOADING AND WEAR TESTS

| | SPECTRA® 900 | Aramid |
|---|---|---|
| Cyclic Sheave - 12 Strand Braid (10 Cycles/Min, 4000 Lb Tensile Load) Cycles to Break | 10,231 | 1212 |
| Oscillating Bar - 0.5 In. Rope (1.5 Cycles/Min, 1700 Lb Tensile Load) Cycles to Break | 883 | 111 |

**Figure 5.** *Ballistic performance of SPECTRA® fabrics.*




.22 CAL 17 GR FSP

**Figure 6.** *Ballistic performance of Spectra® and Aramid composites.*

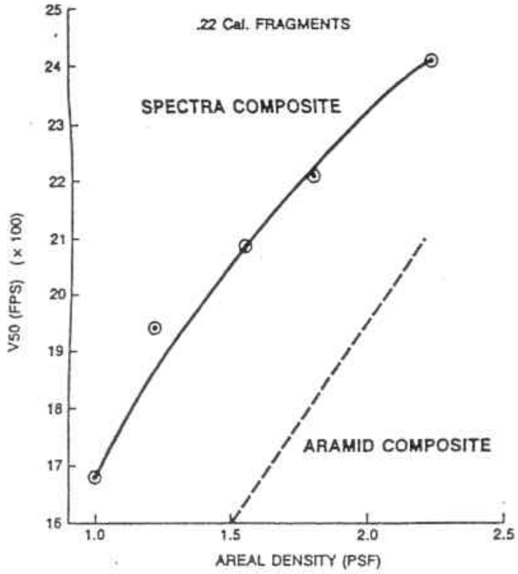



**Figure 7.** *Spectra® fabric ballistic performance at elevated temperatures.*

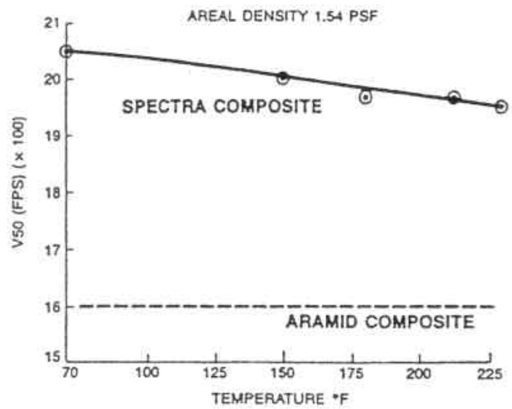
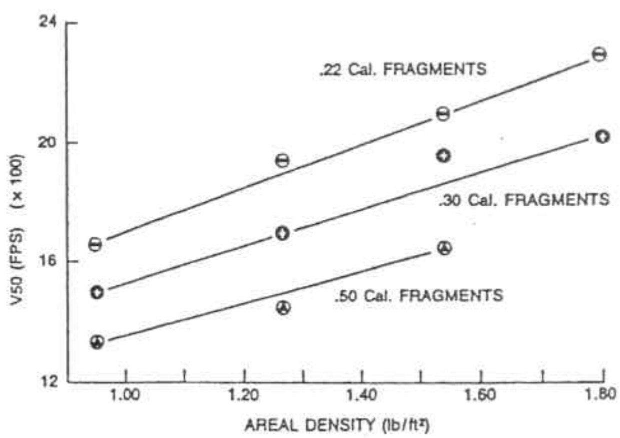



**Figure 8.** *Spectra® composite ballistic protection versus .22, .30 & .50 caliber fragments.*




*DePuy Mitek, Inc. v. Arthrex, Inc.*
*C.A. No.04-12457 PBS*
***DMI003387***

## TABLE 5
## RESISTANCE TO HANDGUN AMMUNITION OF SPECTRA® AND ARAMID COMPOSITES

| Ammunition | No. | Armor System | AD (PSF) | V50 (FPS) |
|---|---|---|---|---|
| .357 Cal. 158 grain JSP | 1 | Spectra/Vinylester 411-45 | 0.62 | 1220 |
| | 2 | Spectra/Vinylester 411-45 | 1.12 | 1443 |
| | 3 | Kevlar/Polyester | 1.15 | 1281 |
| | 4 | Spectra/Vinylester 411-45 | 1.36 | 1481 |
| | 5 | Kevlar/Polyester | 1.49 | 1311 |
| 9mm 124 grain FMJ | 6 | Spectra/Vinylester 411-45 | 0.62 | 1082 |
| | 7 | Spectra/Latex | 0.70 | 1200 |
| | 8 | Spectra/Vinylester 411-45 | 0.83 | 1173 |
| | 9 | Spectra/Latex | 1.01 | 1454 |
| | 10 | Spectra/Latex | 1.23 | 1594 |
| | 11 | Kevlar/Polyester | 1.28 | 1241 |
| | 12 | Kevlar/Polyester | 1.46 | 1372 |
| | 13 | Spectra/Latex | 1.53 | 1624 |

Products: Spectra 1000 and Kevlar 29

## TABLE 6
## INSTRUMENTED IMPACT OF FABRIC COMPOSITES

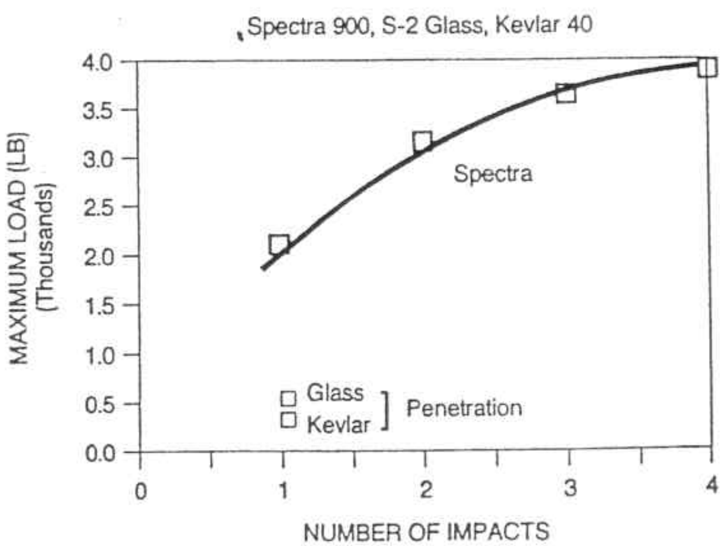
**Resin:** Epoxy Resin

**Fiber Vol. Loading:** 60%

| Fiber | Treatment | Max Load (Lb) | Energy At Max Load (Ft-Lb) | Total Energy (Ft-Lb) | Observation |
|---|---|---|---|---|---|
| SPECTRA 900 | TN[1] | 1660 | 47.4 | 54.5 | No Penetration |
| SPECTRA 900 | TP[2] | 1030 | 12.0 | 28.0 | Penetration |
| Kevlar 49 | EC[3] | 254 | 1.3 | 6.7 | Penetration |
| S-2 Glass | EC | 370 | 1.8 | 4.4 | Penetration |
| HM Graphite | EC | 133 | 1.2 | 2.5 | Penetration |

[1] No Treatment [2] Plasma Treatment [3] Epoxy Compatible

**Figure 9.** *Repetative impact of Spectra® composites.*




DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI003388

## TABLE 7
## IMPACT ABSORPTION OF SANDWICH COMPOSITES

**Core:** ½ in. honeycomb (3 lb./cu. ft.)
**Resin:** Epoxy (Epon 826)

| Skin | No. of Layers | Energy to Peak Force (ft. lb.) | Total Energy Absorbed (ft. lb.) |
|---|---|---|---|
| SPECTRA 900 | 1 | 22.4 | 61.5 |
| Aramid | 1 | 0.7 | 2.3 |
| SPECTRA 900 | 3 | 33.5 | 59.8 |
| Aramid | 3 | 1.5 | 10.5 |

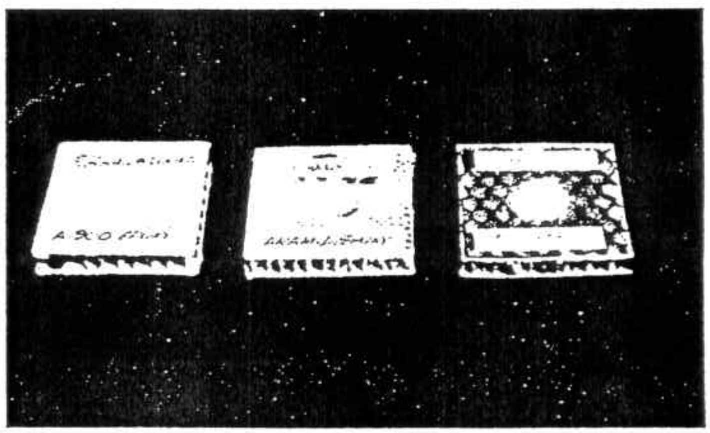


**Figure 10.** *Hailstorm test on Type A composite sandwich panels courtesy of Norton Company, Ravenna, OH.*

## TABLE 8
## FIBER ELECTRICAL PROPERTIES

| Material | Dielectric Constant | Loss Tangent |
|---|---|---|
| SPECTRA | 2.0–2.3 | 0.0002–0.0004 |
| E-Glass | 4.5–6.0 | 0.0060 |
| Aramid | 3.85 | 0.0100 |
| Quartz | 3.78 | 0.0001–0.0002 |

**Figure 11.** *Transmission versus relative thickness for flat panels at 8.5 GHZ.*

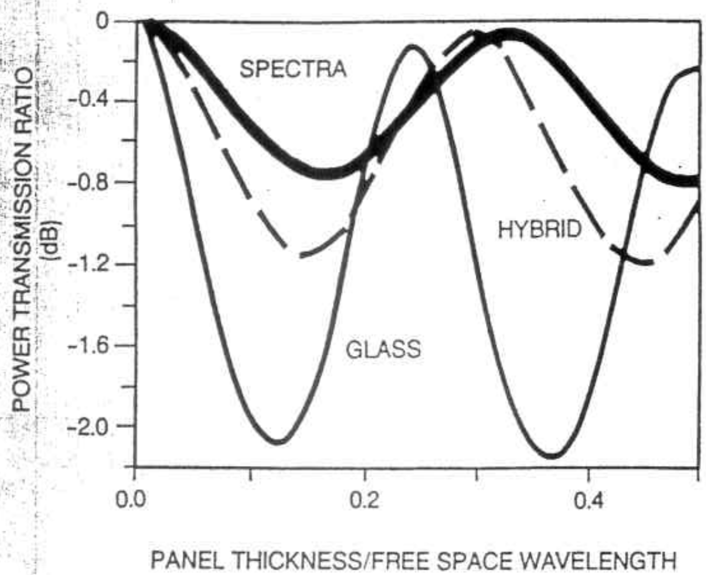
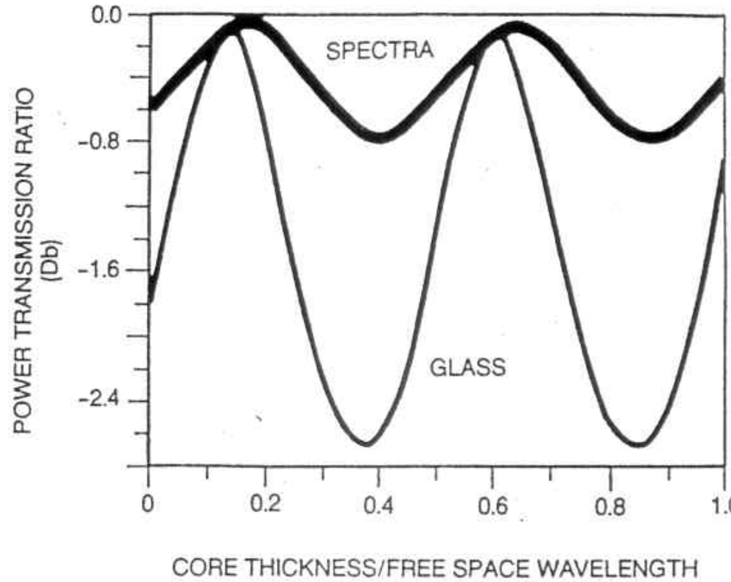



**Figure 12.** *Transmission versus relative thickness Type A, sandwich radome test panel at 8.5 GHZ.*




## TABLE 9
## PROPERTIES OF UNIDIRECTIONAL COMPOSITES (NON TREATED FIBER)

| | Spectra® 900 | Spectra® 1000 |
|---|---|---|
| Axial tensile strength ($10^3$ psi) | 174 | 217 |
| Axial tensile modulus ($10^6$ psi) | 5.8 | 9.1 |
| Axial strain to failure (%) | 3.8 | 2.6 |
| Major Poisson's Ratio | 0.32 | 0.28 |
| Transverse tensile strength ($10^3$ psi) | 1.4 | 1.5 |
| Transverse tensile modulus ($10^6$ psi) | 0.6 | 0.2 |
| Axial compressive strength ($10^3$ psi) | 15.8 | 16.0 |
| Axial compressive modulus ($10^6$ psi) | — | 3.6 |
| Short beam shear strength ($10^3$ psi) | 4.0 | 2.5 |

# EXHIBIT 4

US005314446A

# United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] **STERILIZED HETEROGENEOUS BRAIDS**

[75] Inventors: **Alastair W. Hunter**, Bridgewater; **Arthur Taylor, Jr.**, Plainfield, both of N.J.; **Mark Steckel**, Maineville, Ohio

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] **Int. Cl.**[5] .......... **D04C 1/00**

[52] **U.S. Cl.** .......... **606/231**; 606/228; 87/7; 87/9; 428/370

[58] **Field of Search** .......... 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] **References Cited**

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| 3,636,956 | 1/1972 | Schneider | 128/335.5 |
| 3,942,532 | 3/1976 | Hunter et al. | 128/335.5 |
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| 4,470,941 | 9/1984 | Kurtz | 264/136 |
| 4,624,256 | 11/1986 | Messier et al. | 128/335.5 |
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| | | | |
|---|---|---|---|
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| WO86/00020 | 1/1986 | PCT Int'l Appl. | A61L 17/00 |
| 2082213 | 8/1980 | United Kingdom . | |
| 2218312A | 11/1989 | United Kingdom | A01K 91/00 |

*Primary Examiner*—George F. Lesmes
*Assistant Examiner*—Chris Raimund
*Attorney, Agent, or Firm*—Hal Brent Woodrow

[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

**12 Claims, 3 Drawing Sheets**

FIG-1

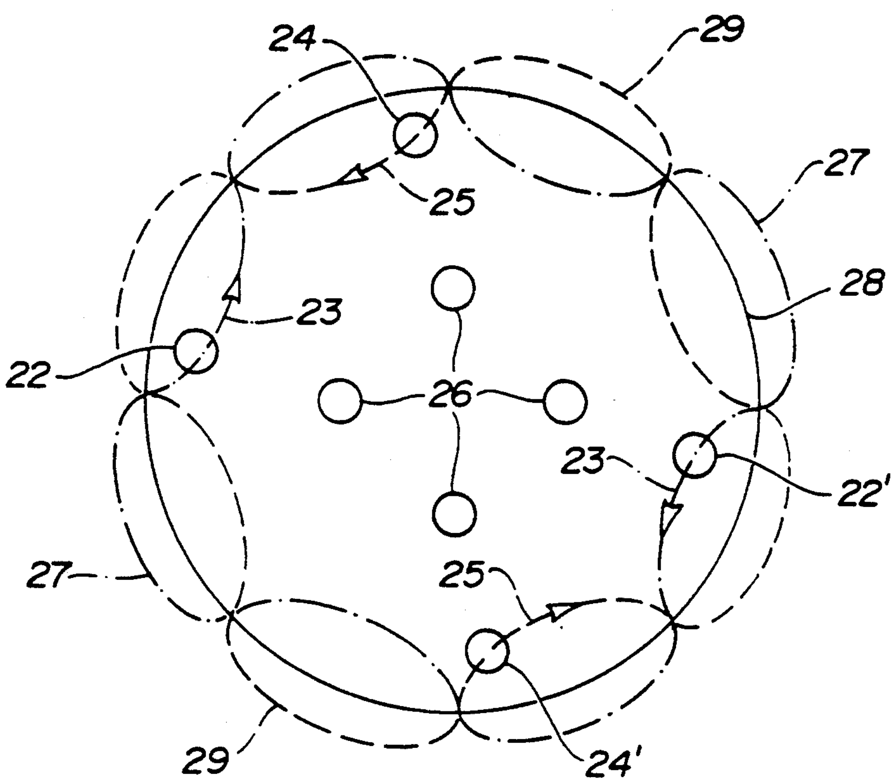


FIG-2

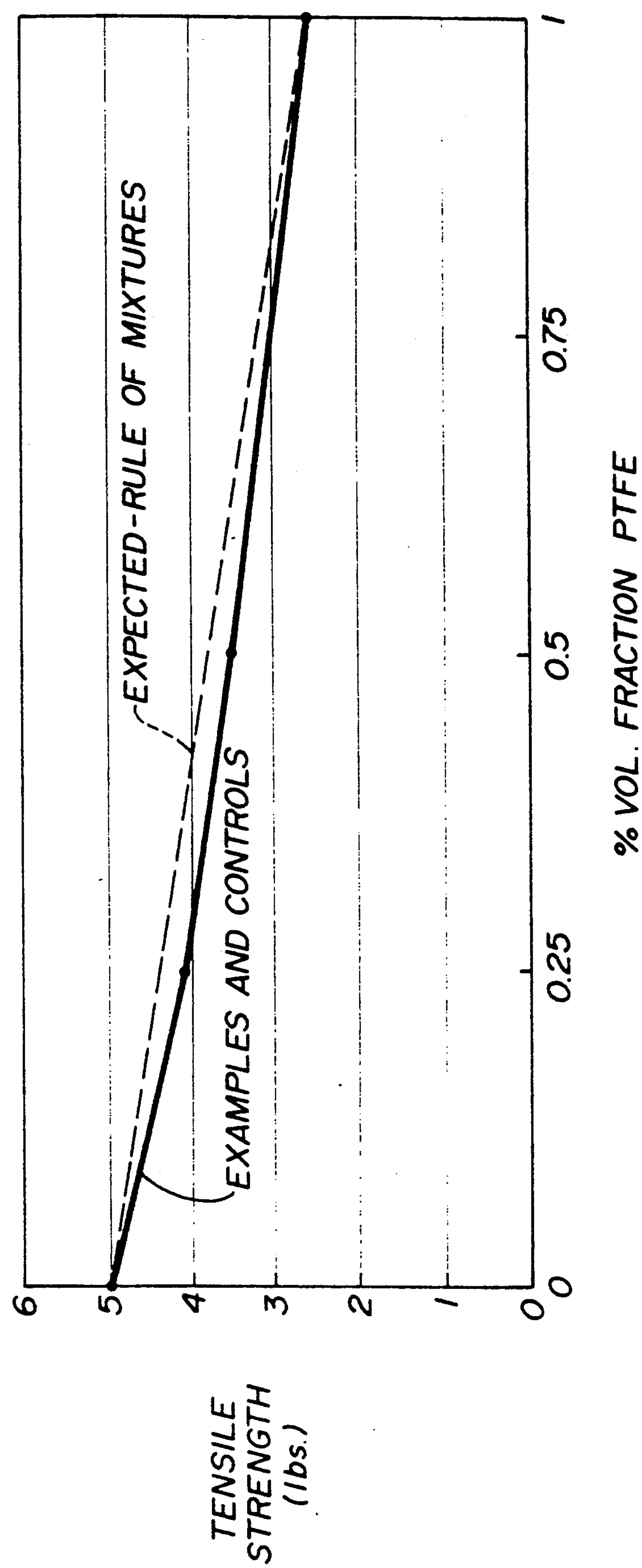
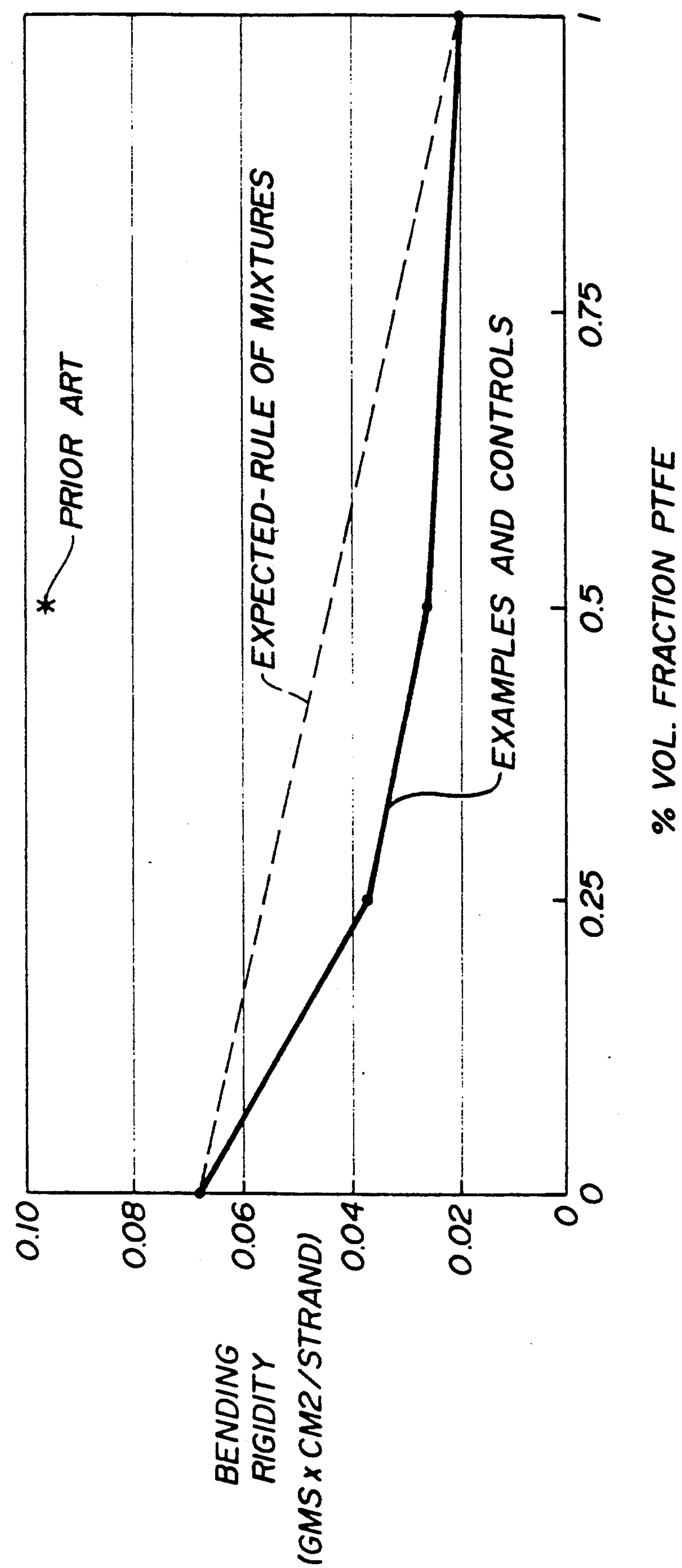

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE
BENDING RIGIDITY (GMS x CM2/STRAND)

# STERILIZED HETEROGENEOUS BRAIDS

## BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent $\epsilon$-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

## SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

## DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers **22**, **22'** and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves



braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

## EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

| | USP DIAMETER (mils) | TENSILE STRENGTH (lbs) | KNOT STRENGTH (lbs) | BENDING RIGIDITY (gm × cm²) | KNOT STABILITY (# of throws) |
|---|---|---|---|---|---|
| CONTROL I | 10.68 | 4.98 | 3.14 | 0.0680 | 4 |
| CONTROL II | 9.11 | 2.58 | 2.04 | 0.0196 | 7 |
| EXAMPLE I | 9.71 | 3.55 | 2.41 | 0.0257 | 5 |
| EXAMPLE II | 10.35 | 4.10 | 2.67 | 0.0371 | 5 |
| PRIOR ART I | 8.81 | | | 0.0966 | |

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)\,(P_a)+(Vf_b)\,(P_b)$$

where $P_c$ is a composite property (such as tensile strength or modulus), $P_a$ and $P_b$ are the properties of the components a and b, and $Vf_a$ and $Vf_b$ are the volume fractions of components a and b. This behavior is clearly observed in FIG. **2**, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. **3** as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. **3**. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

**1**. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

**2**. The surgical suture of claim **1** wherein the suture is attached to a needle.

**3**. The surgical suture of claim **1** wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

**4**. The surgical suture of claim **3** wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

**5**. The surgical suture of claim **4** wherein the first set of yarns is PTFE.



**6**. The surgical suture of claim **5** wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

**7**. The surgical suture of claim **6** wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

**8**. The surgical suture of claim **1** wherein the second set of yarns is PET.

**9**. The surgical suture of claim **8** wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

**10**. The surgical suture of claim **9** wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

**11**. The surgical suture of claim **1** wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

**12**. The surgical suture of claim **8** wherein the suture is attached to a needle.

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# EXHIBIT 5

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS

COPY

DePUY MITEK, INC.,
Plaintiffs,

vs.

ARTHREX, INC., a Delaware corporation,
Defendants.

DEPOSITION of DR. MARK G. STECKEL, called as a witness by and on behalf of the Defendant, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the Courtyard Marriott, 423 Speen Street, Natick, Massachusetts, on Thursday, 26 January, 2006, commencing at 10:44 a.m.

**Q. Yes, one of the things. I didn't mean that to be the only thing.**

A. Okay. Well --

**Q. That's fine.**

A. Yeah.

MR. BONELLA: Object to form.

**Q. I asked you if you needed a clarification to do that.**

A. Yeah.

**Q. So, that's why.**

A. Okay. So, yes, that was one of the things that it could have contributed to.

**Q. Anything else on handling properties?**

MR. BONELLA: Object to form.

A. It's been a while since I've been in the suture business, but I can't think of anything else that it would have -- that it would relate to, other than what we just described for handling.

**Q. Is it -- how about how the knot is tied -- knot tie-down, or is knot tie-down part of the same thing as chatter?**

A. Knot tie-down is part of the same handling properties. And the -- how tight the knot gets is also related, and that's -- going back to the question, if I could, on knot strength, the

Ethicon had multiple development programs going, some of which were to make a product that were -- had better properties than silk, and silk has really good handling properties. Some of them had to do with higher strength sutures. Some of them had to do with different biologic profiles in terms of strength retention over time. And the initial discussions were how can we address those types of problems with a combination of fiber types.

So, the initial conversations -- and one of the avenues that came out of that was this maybe opportunity to have a suture that has strength better than silk, but pliability like silk. So, that was one of them.

**Q. Okay.**

A. And that was one that Al and Art had considered in the past. Again, I'm not clear how far they took that in the past, but they at least considered that. And that was one that we elected to pursue earlier than later, because we had the materials, essentially. We thought it was good opportunity.

**Q. So, if I understand your testimony -- at least at the very beginning stage you wanted something that was stronger than silk but handled**

**as well as silk, is that --**

A. That was certainly one of the embodiments we were going after.

**Q. As the -- as the project -- as the project progressed and as you applied for a patent, is it correct that you were trying to get something that handled better than a homogenous braid but didn't lose strength -- appreciably lose strength from the conventional homogenous braid?**

A. The overall project, yeah, I think that was -- that would be a fair assessment of the objective of the overall project.

**Q. All right. And the conventional homogenous braid that you were talking about that you wanted to not lose appreciative strength then was Ethibond, is that correct?**

A. Right. Ethibond -- well, Ethibond, you know, had good strength, but maybe not as good handling properties as silk,.

**Q. Right.**

A. Silk had lower strength, good handle properties, and again, one of the concepts was we -- maybe we could get the best of both.

**Q. All right. But as you applied for the 446 patent, was it the object there to have something**

**Q. Would that include PET?**
A. It would include, essentially, all of the current -- all of Ethicon's non-absorbable multifilaments at the time, which would include PET, nylon, silk -- that's it.
**Q. So, if I understand your testimony --**
A. Yes.
**Q. -- you had, at least in your mind --**
A. Yes.
**Q. -- the idea of braiding together Dyneema and PET.**
A. It was one of the combinations, yes.
**Q. And did you have a view -- and when did you have this idea?**
A. This -- this would date back to the early conversation with Al Hunter in terms of what benefits could we derive from forming composites of dissimilar fibers.
**Q. Did you have -- in formulating this idea, did you have any sort of belief that if you put Dyneema together with PET, it would lead to an acceptable suture?**
A. It would lead to a suture with potentially improved properties over Ethibond.
**Q. Did you have a belief as to whether that**

**would be an acceptable suture?**

MR. BONELLA: Objection. Asked and answered.

A. We had a belief that it could lead to -- as you're saying -- an acceptable suture. There were other issues that we didn't know. For example, how the -- how polyethylene behaved in the body. So, it was a high priority. Polyethylene, even though there was an interest, it wasn't a -- it wasn't something that was a high priority at the time.

**Q. The thought didn't cross your mind that, Oh, this would make an unacceptable suture to put Dyneema together with PET?**

A. My recollection was -- an unacceptable suture or an acceptable?

**Q. An unacceptable suture.**

A. Well, the concern with any of the very high-strength fibers was always knot strength, and that was true whether it was Dyneema, Spectra, Kevlar, etcetera. So, the general view was, I mean, all of those -- 100 percent, all of those, Ethicon evaluated at one point as a suture material. They're the world's biggest suture material company. And all of them there was an

interest in how do you improve the knot strength of them, and can you -- that was -- that was something we discussed.

**Q. I'm not sure I understand your answer.**

A. Go ahead.

**Q. And I'm trying to --**

A. Sure.

**Q. When you had this idea that you could blend Dyneema together with PET, were you -- did you believe it would make an acceptable suture or an unacceptable suture?**

A. No. We believed -- we believed that that could offer a suture with straight tensile that was better than Ethibond, and you know, could potentially solve the knot issues, and again, that was a generic view for all of the high-tenacity fibers.

**Q. You thought it was a good idea --**

A. Yes. Yes.

**Q. -- rather than a bad idea?**

A. No, we viewed -- we viewed that as a potential good idea.

**Q. And you didn't think, Oh, that's a bad idea.**

MR. BONELLA: Objection. Asked and

# EXHIBIT 6

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[redacted]

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## TITLE OF THE INVENTION

## STERILIZED HETEROGENEOUS BRAIDS

## BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.



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U.S. Patent 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Patent 4,624,256 discloses a suture coating copolymer of at least 90 percent $\epsilon$-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

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An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Patent 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

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More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Patent 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite

sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by Figure 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

## SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying

the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

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## BRIEF DESCRIPTION OF THE DRAWINGS

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Figure 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

Figure 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

Figure 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

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## DETAILED DESCRIPTION OF THE INVENTION

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For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at

least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Patent Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Patent Nos. 4,959,069 and 5,059,213.

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The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns,



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respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, $\epsilon$-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

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Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle

of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below



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about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of Figure 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and 24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of Figure 1 are dispensed upward

with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

4C In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. 4C In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 4C 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in Figure 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 4C 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing

stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Patent 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is

determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

C.L

## EXAMPLES

P

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Patent 4,470,941.

B

B F

## CONTROL I

C.L

PB33

L

FIBER MATERIALS: An 8x0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

P

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each



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carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225 C°.

B

B

B

CL

CONTROL II

PB33

**FIBER MATERIALS**: An 8x0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

P

**PROCESSING:** The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

B

CL

EXAMPLE I

PB33

**FIBER MATERIALS**: An 8x0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

B

P

**PROCESSING**: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm.

B

B

The braid is scoured and hot stretched per the conditions described in CONTROL I.

CL

## EXAMPLE II

PB

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PB

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

CL

## PRIOR ART I

PB

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PB

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300 C° and for a longer residence time to facilitate melting of the PET fibers.

P

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

| | USP DIAMETER (mils) | TENSILE STRENGTH (lbs) | KNOT STRENGTH (lbs) | BENDING RIGIDITY (gmXcm²) | KNOT STABILITY (# of throws) |
|---|---|---|---|---|---|
| CONTROL I | 10.68 | 4.98 | 3.14 | 0.0680 | 4 |
| CONTROL II | 9.11 | 2.58 | 2.04 | 0.0196 | 7 |
| EXAMPLE I | 9.71 | 3.55 | 2.41 | 0.0257 | 5 |
| EXAMPLE II | 10.35 | 4.10 | 2.67 | 0.0371 | 5 |
| PRIOR ART I | 8.87 | | | 0.0966 | |

TI 70X

PS

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

STi I

$$P_c = (Vf_a)\ (P_a) + (Vf_b)\ (P_b)$$

PSPSII

where $P_c$ is a composite property (such as tensile strength or modulus), $P_a$ and $P_b$ are the properties of the components a and b, and $Vf_a$ and $Vf_b$ are the volume fractions of components a and b. This behavior is clearly observed in Figure 2, which shows a plot of tensile strength versus



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volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in Figure 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the <u>bending moment-radius of curvature</u> plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

I

FB

U.S. Patent 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and Figure 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

B



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WHAT IS CLAIMED IS:

1. A heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and:

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

2. The heterogeneous braid of claim 1 wherein the first and second fiber-forming materials are nonmetallic.

3. The heterogeneous braid of claim 2 wherein the first and second fiber-forming materials are synthetic fiber-forming polymers.

4. The heterogeneous braid of claim 3 wherein the synthetic fiber-forming polymers are bioabsorbable.

5. The heterogeneous braid of claim 4 wherein the bioabsorbable polymers are derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactide, p-dioxanone, ε-caprolactone, trimethylene carbonate, and mixtures thereof.

6. The heterogeneous braid of claim 3 wherein the fiber-forming polymers are nonabsorbable.

3 ~~7~~. The surgical suture ~~heterogeneous braid~~ of claim 1 ~~or 6~~ wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4 ~~8~~. The surgical suture ~~heterogeneous braid~~ of claim 3 ~~7~~ wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

~~9. The heterogeneous braid of claim 8 wherein the first set of yarns is PTFE, FEP, PFA, PVDF, PETFE, PP or PE.~~

5 ~~10~~. The surgical suture ~~heterogeneous braid~~ of claim ~~4~~ ~~9~~ wherein the first set of yarns is PTFE.

6 ~~11~~. The surgical suture ~~heterogeneous braid~~ of claim 5 ~~10~~ wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7 ~~12~~. The surgical suture ~~heterogeneous braid~~ of claim 6 ~~11~~ wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

~~13. The heterogeneous braid of claim 12 wherein the second set of yarns is PET, nylon or aramid.~~

8 ~~14~~. The surgical suture ~~heterogeneous braid~~ of claim 1 ~~12~~ ~~13~~ wherein the second set of yarns is PET.

~~15. The heterogeneous braid of claim 14 wherein each yarn from the first set is in direct intertwining contact with a yarn from the second set.~~

~~16. The heterogeneous braid of claim 15 wherein the braid encloses a core of longitudinally extending yarns.~~



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17. The heterogeneous braid of claim 16 wherein the longitudinally extending yarns are PET.

9 ~~18~~. The surgical suture ~~heterogeneous braid~~ of claim 8 ~~17~~ wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10 ~~19~~. The surgical suture ~~heterogeneous braid~~ of claim 9 ~~18~~ wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11 ~~20~~. The surgical suture ~~heterogeneous braid~~ of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

21. A surgical suture comprising the heterogeneous braid of claim 1.

22. A surgical suture comprising the heterogeneous braid of claim 19.

2 ~~23~~. The surgical suture of claim 1 ~~21~~ wherein the suture is attached to a needle.

12 ~~24~~. The surgical suture of claim 8 ~~22~~ wherein the suture is attached to a needle.

ETH-782

23

07/838,511




ABSTRACT

SA Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

PA Heterogeneous braids are useful for preparation of surgical sutures and ligatures. E7


ETH-782

# EXHIBIT 7

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | | ATTORNEY DOCKET NO. |
|---|---|---|---|---|
| 07/838,511 | 02/19/92 | HUNTER | A | ETH-782 |

| EXAMINER | |
|---|---|
| RAIMUND, C | |
| ART UNIT | PAPER NUMBER |
| 1504 | 3 |

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

DATE MAILED: 07/08/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on ________ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ ________

**Part II SUMMARY OF ACTION**

1. ☑ Claims 1 - 24 are pending in the application.

   Of the above, claims 1 - 20 are withdrawn from consideration.

2. ☐ Claims ________ have been cancelled.
3. ☐ Claims ________ are allowed.
4. ☑ Claims 21 - 24 are rejected.
5. ☐ Claims ________ are objected to.
6. ☑ Claims 1 - 24 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on ________. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on ________ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on ________, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ________; filed on ________.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

PTOL-326 (Rev. 9-89)

EXAMINER'S ACTION

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000186

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-20, drawn to a heterogeneous braid, classified in Class 57, subclass 243.

II. Claims 21-24, drawn to a surgical suture, classified in Class 600, subclass 231.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a fishing line and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Matthew S. Goodwin on June 23, 1992 a provisional election was made without traverse to prosecute the invention of Group II, claims 21-24. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-20 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Burgess (U.K. Patent Application No. 2,218,312A).

Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon. Such a braid is disclosed to have the low stretchability of polyethylene and the low coefficient of friction of polyester. (See page 1). It is therefore known to braid filaments of two dissimilar polymers together to form a structure which embodies the desirable properties of each fiber.

Braided sutures are well known in the art. Many of the requirements of sutures are comparable to those of fishing line-strength, low stretchability, flexibility, low coefficient of friction etc. Indeed, many of the same materials are used for both of these applications. It would therefore have been

obvious, in view of Burgess, to use a heterogeneous braid for a suture. Claims 21 and 23 are therefore unpatentable over Burgess.

Synthetic, fiber forming polymers are widely employed as filaments in braided sutures. In German Patent Application DE 2949920A1, for example, surgical sutures made from braided polytetrafluoroethylene (PTFE) fibers or polyester fibers are disclosed. As polyester fibers are noted for their strength and PTFE fibers for their low coefficient of friction, it would have been obvious to use a braid comprising both types of filaments as a suture.

It is also known in the art to a braid around longitudinally extending core filaments. Ohi et al, for example, disclosure a core comprising a plurality of synthetic fiber filaments (column 1, lines 57-60). Polyester filament are specifically disclosed (column 2, lines 4-9). It would therefore have been obvious to dispose a heterogeneous braid comprising polyester and polytetrafluoroethylene fibers around a core of polyester fibers to form a suture. Claims 22 and 24 are therefore unpatentable over Burgess.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-3452.

Chris Raimund

Chris Raimund:jp
July 06, 1992

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

*DePuy Mitek, Inc. v. Arthrex, Inc.*
*C.A. No.04-12457 PBS*
***DMI000190***

# EXHIBIT 8

(12) UK Patent Application (19) GB (11) 2 218 312 (13) A

(43) Date of A publication 15.11.1989

(21) Application No 8911088.6

(22) Date of filing 15.05.1989

(30) Priority data
(31) 8811498 (32) 14.05.1988 (33) GB

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(51) INT CL⁴
A01K 91/00, D04C 1/12

(52) UK CL (Edition J)
A1A A19
D1K K14
U1S S1022

(56) Documents cited
None

(58) Field of search
UK CL (Edition J) A1A, D1K
INT CL⁴ A01K, D04C

(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyester and/or nylon, and the braid may be coated with a sheath of polyurethane.

GB 2 218 312 A

2218312



"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple and smooth sheath of polyurethane and this may be carried out by a simple immersion process in liquid polyurethane. It will alter the characteristics (such as buoyancy and strength) in a predictable manner, but its main purpose is to prevent saturation of the interstices of the braid. In very cold conditions, such as fishing through holes in ice, water having worked its way into the braid will freeze and impart a brittleness that can lead to breakage.

SL/SCS

## CLAIMS

1. A fishing line of braided connstruction, some braid filaments being of high tenasile polythene thread and other filaments being of pollyester and/or nylon.

2. A line as claimed in Claim 1,, wherein the other filaments include polyester mmulti-filaments.

3. A line as claimed in Claim 1 or 2, wherein the other filaments include nylon monofilaments.

4. A line as claimed in Claim 1., 2 or 3, wherein the braid is coated by a sheath of polyyurethane.

5. A line as claimed in any preeceding Claim, wherein the polythene is that sold undeer the Trade Mark DYNEEMA.



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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
**DMI000125**

# EXHIBIT 9

ETH-78

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair Hunter et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 6, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

Matthew Goodwin
(Signature)

August 6, 1992
(Date of Signature)



Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Responsive to the Office Action of July 8, 1992, please reconsider the above-identified application in view of the following remarks.

REMARKS

1. Restriction to the invention of either Group I, claims 1-20, or Group II, claims 21-24, was required. Applicants reaffirm without traverse to prosecute the invention of Group II, claims 21-24. This election is made without prejudice to Applicants' right to file a divisional application directed to the non-elected invention of Group I, claims 1-20.

2. Claims 21-24 were rejected under 35 USC §103 as being unpatentable over Burgess. The Examiner has asserted that it would have been obvious in view of Burgess to use a heterogeneous braid for a suture. Applicants respectfully traverse this rejection.

The Examiner mistakenly believes that the requirements for a braided suture are comparable to those of a fishing line. However, nothing could be further from the truth.

One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement may be the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact. If the knot fails, then the wound can reopen and consequently the braided suture has failed as well.

Applicants recognized the importance of knot strength when attempting to overcome the shortcomings of the braided sutures disclosed in the art. In preferred embodiments of the invention, Applicants' claimed suture exhibits improved handling properties without sacrificing physical strength or knot security (see the specification at page 5, lines 4-7). In addition, numerous braided sutures were tested to determine their knot strength and knot security (see the examples at the end of the specification). The determination of knot security is described in the specification at page 12, lines 26-33.

In contrast, knot strength is not even mentioned in Burgess. Although it may be argued that it may be necessary to secure a knot on a fishing line to hold the hook to the line, the security and strength of the knot are not nearly as critical for this application. In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction, as set forth in more detail below.

Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability (see Burgess at page 1, lines 12-13). Although this thread has great strength properties, it suffers from

low elongation and, in turn, poor knot strength properties. This is a good idea for a fishing line because high strength and low elongation, or low stretchability, are important criteria. Low elongation is an important requirement for a fishing line because it makes it possible for the fisherman to apply force on the hook when, for example, the fish is caught. If the line were stretchable, then the force exerted by the fisherman would be taken up by the stretching action of the line. This would clearly be an undesirable property for a fishing line to exhibit. Therefore, the property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security.

In addition to the contrasting requirements for braided sutures and fishing line resulting from the critical need to tie strong and secure knots on braided sutures, other requirements concerning the knot make the braid for a fishing line unsuitable for use as sutures. For example, a surgeon must be able to make a conventional square knot at a very fast pace for patient safety. Clearly, a knot on a fishing line for a hook can be made at a much slower pace, and with a much more complex knot. Also, it is necessary during suturing to form a pre-knot on the braided suture, and the pre-knot must be subsequently slid down the suture until it is adjacent the body tissue desired to be stitched. Once the knot is placed at the desired location, additional throws on the knot can be added for knot security. This requires a braided suture which is stretchable and resilient so that this operation can be performed. Obviously, there is no such similar requirement for a fishing line.

In view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a

suture, then he would inevitably design an unacceptable suture. Accordingly, Applicants respectfully submit that the rejection is in error and therefore it should be withdrawn.

It is noted that the Examiner has discussed German Patent Application DE 2949920 A 1 and Ohi et al. as evidence of the state of the art concerning the types of filaments used in braided sutures, and core/sheath braid construction. Applicants do not wish to rely on these specific limitations set forth in claims 22 and 24 for patentability, but instead rely on the inventive features set forth in the broader independent claim, claim 21.

Accordingly, for the reasons set forth above, Applicants respectfully request the Examiner to withdraw the rejection of claims 21-24 under 35 USC 103 as being unpatentable over Burgess.

3. Since all formal requirements appear to have been met, except for the submission of formal drawings, and claims 21-24 are patentable over the art of record, Applicants respectfully solicit a Notice of Allowability.

Respectfully submitted,

Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

# EXHIBIT 10

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

This amendment is responsive to the Office Action of March 18, 1993.



IN THE CLAIMS

Please amend claim 21 as follows:

(Once Amended)

CM

1 ~~21~~. A surgical suture [comprising] consisting essentially of a [the] heterogeneous braid [of claim 1] composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

Pl a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

Pl b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

Pl c) optionally a core.

20

CLAIM 2

**REMARKS**

Please note that the attorney prosecuting this application for the assignee, Johnson & Johnson, is now Hal Brent Woodrow (Reg. No. 32,501). This change has been authorized by the Associated Power Attorney submitted herewith. No change in the address for correspondence is necessary.

Claim 21 has been amend to place this claim in proper form for allowance. Claim 21 as amended claims a heterogeneous braid composed of a first and second set of yarns. The first set of yarns are made of a fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP, and PE materials. The second set of yarns are made of a fiber-forming material selected from the group consisting PET, nylon and aramid materials. Support for there amendments may be found in the specification on page 4, lines 12-22 and page 8, lines 3-23. Accordingly, applicants request entry of this amendment and reconsideration of claim 21.

The rejection of claim 21 under 35 U.S.C. §102(e) as being anticipated by Kaplan et al. has been reviewed. However, applicants respectfully submit that claim 21 as amended is not anticipated by Kaplan. Kaplan, as stated by the Examiner, describes a connective tissue prosthesis comprising a braided sheath yearn component and a core yarn component. The sheath yarn being a biocompatible yarn that is bioabsorbable or semi-bioabsorbable (column 9 lines 10-12). In one embodiment the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition (column 9 line 25-27). Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn. Accordingly, Kaplan et al. does not anticipate claim 21 under 35 U.S.C. § 102(e). Therefore, applicants request reconsideration and withdrawal of the rejection of claim 21 as being anticipated by Kaplan et al.

Applicants have also reviewed the rejection of claims 21-24 under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al. However, applicants respectfully submit that claims 21-24 are patentable over these documents.

Doddi et al. describes (column 9, lines 46-56) multifilament sutures composed of p-dioxanone and/or 1,4 dioxepan-2-one and alkyl substituted derivatives that may be woven, braided or knitted, either alone or in combination with nonabsorbable fibers. Although Doddi is a significant contribution to the art, Doddi does not describe heterogeneous braids formed from a first set of yarn composed of a plurality of filaments formed from materials selected

from the group consisting of PTFE, FEP, PFA PVDF, PETFE, PP and PE; and a second set of yarn composed from a plurality of filaments formed from materials selected from the group consisting of PET, nylon and aramid. Accordingly, Doddi alone would not render the present invention obvious.

Kaplan et al. as discussed previously describes a prosthesis comprising a core component and a braided sheath component. The sheath component which is designed to "erode over time" (column 9, line 52) to leave only the nonabsorbable core component. The sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments. Applicants, therefore, respectfully submit that Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e. PTFE) and a second set of nonabsorbable yarn (i.e. PET). In fact, Kaplan teaches away from this combination.

In column 2, Kaplan describe one of the objects of their invention as being "a prosthesis being formed of a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-absorbable sheath yarn so as to exhibit the stress-strain properties of natural tissue" (column 2, lines 36-41). In column 4, Kaplan describes fluorinated hydrocarbons, polypropylene and polyethylene as elastic core polymers as opposed to the inelastic sheath polymers desired in the sheath. Thus, Kaplan appears to suggest that the sheath yarns listed by the applicant in claim 21 should not be used as in sheaths. Applicants respectfully submit that in view of Kaplan teaching away from the present invention that the combination of Kaplan with Doddi does not render the present invention obvious. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 21-24.

The citation of Block (U.S. Patent No. 3,527,650) has also been considered, but is respectfully submitted to be non-analogous art. Block describes the use of PTFE particles on the external surface of a PET suture as a lubricant. Block, however, does not suggest or disclose PTFE fiber as having a lubricating effect. Therefore, Block's use of PTFE particles does not suggest or disclose the use of PTFE fibers in braids.

Applicants also wish to alert the Examiner to the applicants' intent to change the inventorship because of the reduced scope of the claims. Dennis D. Jamiolkowski will no longer appear as an inventor if the present claims are allowed. Papers to effectuate this changed inventorship will be submitted when one or more of the present claims are indicated to be allowable.

Respectfully requested,

Hal Brent Woodrow
Hal B. Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
Date: August 31 1995

# EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

| | | |
|---|---|---|
| **DePuy Mitek, Inc.**<br>**a Massachusetts Corporation**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**Arthrex, Inc.**<br>**a Delaware Corporation and**<br><br>**Pearsalls Ltd.,**<br>**a Private Limited Company**<br>**of the United Kingdom,**<br><br>**Defendants.** | ) | **Civil No. 04-12457 PBS** |

**<u>Expert Report of Dr. David Brookstein</u>**

## I. Background Information

### A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

device "performs substantially the same function in substantially the same way to obtain the same result" ("function/way/result test") as the claimed element.

## V. Direct Infringement

### A. Claim Construction

27. As mentioned above, I understand that the first step in an infringement analysis is to construe the claims. I understand that the Court will determine the meaning of the claim terms in the '446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

"PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

"consisting essentially of" – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

"direct intertwining contact" –means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

"volume fraction of the first set of yarns in the braided sheath and core" means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHWMPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

| **Claims 1, 2, 8, 9, and 12 Limitation** | **"Way" of Limitation Under the Doctrine of Equivalents** | **Way UHMWPE performs its Function in FiberWire™ and TigerWire™** |
|---|---|---|
| a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and | The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set. | At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107). |

58. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct

# EXHIBIT 12

121

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

| | |
|---|---|
| DePuy Mitek, Inc.<br>a Massachusetts Corporation<br><br>Plaintiff,<br><br>v.<br><br>Arthrex, Inc.<br>a Delaware Corporation<br><br>Defendant. | Civil Action No. 04-12457 PBS |

**EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE
CONCERNING INVALIDITY OF U.S. PATENT NO. 5,314,446**

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his expert report as follows.

DSMDB.2050301.1

I have been informed by Mr. Witherspoon that in order for a patent to be valid, the specification must meet the "written description" requirement of 35 U.S.C. § 112, which means that it must reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. I further have been informed that in order for a patent to be valid, it must also satisfy the "enablement" requirement of section 112. That is, I have been informed that one must determine whether the specification, viewed from the perspective of a person skilled in the art, teaches such a person how to make and use the claimed invention without having to resort to undue experimentation.

It is my opinion that the '446 patent specification as filed in 1992 does not reasonably convey to one of ordinary skill in the art that the inventors had possession of UHMWPE. There is no disclosure at all within the '446 patent of using UHMWPE as a suture material. In February 1992, UHMWPE was a well-known, highly specialized fiber material with strength properties that are far superior to those of general purpose PE. Consequently, the two materials are generally used for very different applications and one is not a substitute for the other. It has been my experience that, generally, when UHMWPE is intended to be included for a specified application, there is a special effort to make that fact known. For example, the '575 patent, the Burgess application, the Cohan article, Arthrex's U.S. Patent No. 6,716,234, covering its FiberWire suture, Plaintiff's patent application no. 2005/0149118, covering its Orthocord suture and

# EXHIBIT 13

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

| | | |
|---|---|---|
| **DePuy Mitek, Inc.**<br>**a Massachusetts Corporation**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**Arthrex, Inc.**<br>**a Delaware Corporation and**<br><br>**Pearsalls Ltd.,**<br>**a Private Limited Company**<br>**of the United Kingdom,**<br><br>**Defendants.** | )<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>) | **Civil No. 04-12457 PBS** |

**Expert Report of Dr. Matthew Hermes**

## I. Background Information

### A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post

apparent to one of ordinary skill in the art and that patent specifications need not be as detailed as production specifications.

### D. Actual Reduction to Practice

27. I understand that invention requires a conception and reduction to practice. I understand that conception is the formulation of an idea in one's mind of a definite and permanent idea. I further understand that actual reduction to practice typically occurs when the claimed invention is constructed and evaluated sufficiently to know that it will work for its intended purpose.

## IV. Claim Construction

28. As mentioned above, I understand that the first step in an invalidity analysis is to determine the meaning of the claims. I understand that the Court will determine the meaning of the claim terms in the 446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

"PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

"Consisting essentially of" – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

"Direct intertwining contact" means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

"Volume fraction of the first set of yarns in the braided sheath and core" means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions.

## V. Materials Considered in Forming My Opinions

29. In forming my opinions, I have considered the 446 Patent, its file history, and the reports of Dr. Debi Prasad Mukherjee and John F. Witherspoon, and Peter Dreyfuss's, Brian Hallet's, and Dr. Mark Steckel's, and Mr. Donald Grafton's deposition testimony. A list of the documents that I used in forming my opinions is set forth in Ex. 16.

## VI. Claims 1, 2, 8, 9, & 12 of the 446 Patent Are Not Invalid Over the References Discussed by Dr. Mukherjee

### A. The Level Of Ordinary Skill In The Art

30. I understand that Dr. Mukherjee has opined that a person of ordinary skill in the art, "in February 1992, had an undergraduate degree in engineering or science and several years (*e.g.*, approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications." (Mukherjee at 10). I disagree because this definition of ordinary skill is too broad. It encompasses persons who do not have any relevant technical degrees and relevant experience. For example, Dr. Mukherjee's definition includes someone with no education that is relevant to suture design and no suture design experience.

# EXHIBIT 14

3/6

5120802

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

6:15 - 6:57 MJ
7:05 - 7:17 MJ
7:18 - 7:42 446
7:45 - 7:57 Cohan / Plemmings

| | | |
|---|---|---|
| DePuy Mitek, Inc.<br>a Massachusetts Corporation<br><br>Plaintiff,<br><br>v.<br><br>Arthrex, Inc.<br>a Delaware Corporation<br><br>Defendant. | ) | Civil Action No. 04-12457 PBS |

*DePuy Mitek, Inc. v. Arthrex, Inc.*
*C.A. No.04-12457 PBS*
***MH000109***

## EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE CONCERNING INVALIDITY OF U.S. PATENT NO. 5,314,446

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his expert report as follows.

3/6 Rea

$6^{15}$ - $6^{52}$ Read through
$7^{05}$ - $7^{17}$ Notes

1. 446 was issued
2. Burgess 312 is a cartoon – a muddy & incomplete and poorly defined document – did it become a Brit Patent? Speaks of UHMW PE thread? is that even multifilament yarn. Speaks of nylon multifilament in conjunction w/ PE – No drawing [illegible]
3. 446 teachings on affecting properties of yarn A w/ yarn B may seem to teach away from UHMW PE but the critical principal is mixing yarns & getting better than accepted properties. It doesn't LCMIT A strength B lubricate just suggests it
4. Claim PE and UHMW PE is PE on
   - historical
   - microscopic
   - conventional
   - scientific nomenclature
   - macroscopic basis
   - demonstrable showing of PE fiber

DSMDB.2050301.1

| | |
|---|---|
| EXHIBIT | 193 |
| Deponent | Dr. Hermes |
| Date | 7.25.06 |
| Rptr. | ph |

WWW.DEPOBOOK.COM

# EXHIBIT 15

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

COPY

--------------------------------x

DePUY-MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

vs.

ARTHREX, INC.,

A Delaware Corporation,

Defendants.

--------------------------------x

DEPOSITION OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

June 27, 2006

Reported by:

CONSTANCE S. KENT, CSR, RPR

JOB NO.: 350

**clearer source-based names, correct?**

A. Yes.

**Q. Okay. Is it your understanding that this document is designed to try and clear up an ambiguity that existed?**

A. No, it's my understanding that it's a document describing generic source-based nomenclature.

**Q. What does it mean to you when it says it solves these problems and yields clearer source-based names?**

A. Whatever problems there were, it's attempting to clear them up. I'm sorry, I'm not familiar with what the specific problems were.

**Q. But you agree with me this document in 2001 is an attempt to clear up problems that existed on names?**

A. That's what it says sir, yes.

**Q. Let's -- let's go to Exhibit 18 if we could, please.**

A. Indeed.

**Q. Could you turn to page 193 of this report?**

A. Yes.

**Q. Is it correct that this -- this**

**exhibit is saying that there are deficiencies of source-based nomenclature?**

A. The -- the paragraph beginning the principal deficiency talks in general about a nomenclature problem that has been inherent in defining the names of polymers, yes.

**Q. And if you look further down the paragraph, doesn't it conclude, the paragraph: The rapid advances now being made in the structural determination of polymers will gradually shift the emphasis of polymer nomenclature away from the starting materials and toward the structure of the macromolecules?**

A. That's a -- that is the opinion of the authors.

**Q. Do you have any reason to disagree with the opinions of the authors?**

A. I don't think I have enough knowledge to disagree with those authors.

Having said that, this was published in 1987, 20 years ago, and there's no -- there's no indication in the field of ethylene and polyethylene that anything of that kind is going on these days. Polyethylene is still polyethylene, and the -- the structural details do not appear in the source-based

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

_______________________________________x

DePUY-MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

vs.

ARTHREX, INC.,

ORIGINAL

A Delaware Corporation,

Defendants.

_______________________________________x

DAY 2 OF 2

CONTINUED VIDEOTAPED DEPOSITION

OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

July 25, 2006

Reported by:

PAMELA HARRISON, RMR, CRR, CSR

properties." 01:03:08p

**Q. When you used the -- 01:03:10p**

A. I'm not finished. 01:03:12p

**Q. Okay. I'm sorry, sir. 01:03:13p**

A. It doesn't -- I'm not finished. 01:03:14p

"It doesn't LIMIT," in capital 01:03:18p
letters, "A, strength, or B, lubricity, just 01:03:20p
suggests it." 01:03:27p

**Q. When you used the nomenclature I think 01:03:27p
you said UHMWPE? 01:03:32p**

A. Yes. 01:03:35p

**Q. Does that mean ultra high molecular 01:03:35p
weight PE? 01:03:37p**

A. That did mean ultra high molecular 01:03:38p
weight polyethylene, yes. 01:03:39p

**Q. Right. When you wrote at the end, you 01:03:41p
said, just suggests it, A, strength, and B, 01:03:46p
lubricity, what did you mean by that? 01:03:50p**

A. I meant -- I meant specifically that 01:03:51p
the teachings in the preferred embodiment in 01:03:54p
which -- in which the preferred embodiment 01:03:58p
mentions the relationship of -- the preferred 01:04:02p
embodiment discussing PTFE, that -- in which we 01:04:05p
talk about the strength of the braid and the 01:04:11p
relationship of strength to the braid, that that 01:04:17p

# EXHIBIT 16

# ENCYCLOPEDIA OF POLYMER SCIENCE AND ENGINEERING

## VOLUME 10

## Molecular Weight Determination to Pentadiene Polymers

A WILEY-INTERSCIENCE PUBLICATION
John Wiley & Sons
NEW YORK • CHICHESTER • BRISBANE • TORONTO • SINGAPORE

**Library of Congress Cataloging in Publication Data:**
Main entry under title:

Encyclopedia of polymer science and engineering.

Rev. ed. of: Encyclopedia of polymer science and technology. 1964–
"A Wiley-Interscience publication."
Includes bibliographies.
1. Polymers and polymerization—Dictionaries.
I. Mark, H. F. (Herman Francis), 1895–
II. Kroschwitz, Jacqueline I. III. Encyclopedia of polymer science and technology.

TP1087.E46 1985 668.9 84-19713
ISBN 0-471-80942-X (v. 10)

**Printed in the United States of America**

49. A. Yoneda, K. Hayashi, M. Tanaka, and N. Murata, *Kobunshi Kagaku* **29**, 87 (1972).
50. U.S. Pat. 3,986,629 (Oct. 19, 1976), H. M. Singleton (to Southland Corp.).
51. U.S. Pat. 3,886,106 (May 27, 1975), D. F. Lohr, E. L. Kay, and W. R. Hausch (to the Firestone Tire & Rubber Co.).
52. Ger. Offen. 3,006,743 (Sept. 4, 1980), U. Katsuji and M. Takashi (to Sumitomo Chemical Co., Ltd.).
53. A. Yoneda, K. Sugihara, K. Hayashi, and M. Tanaka, *Kobunshi Kagaku* **30**, 180 (1973).
54. Jpn. Kokai Tokyo Koho 79 53,689 (Apr. 27, 1979) and 79 53,690 (Apr. 25, 1979), T. Kawai, K. Haraguchi, and S. Inou (to Central Glass Co., Ltd.).
55. S. Sherratt in A. Standen, ed., *Kirk-Othmer Encyclopedia of Chemical Technology*, 2nd ed., Vol. 9, Wiley-Interscience, New York, 1966, pp. 807–812.
56. *VANAX-PY, Material Safety Data Sheet*, R. T. Vanderbilt Co., Inc., Norwalk, Conn., Feb. 4, 1985.

D. K. Dandge
New Mexico Institute of Mining and Technology

L. G. Donaruma
University of Alabama in Huntsville

# NOMENCLATURE

Nomenclature, as used in this article, refers to the naming of polymeric materials. The nomenclature of scientific communication is emphasized, although there is generally little reason for differences between scientific and other, eg, commercial, usage.

Since the publication of the first edition of this Encyclopedia, the International Union of Pure and Applied Chemistry (IUPAC) has established the Commission on Macromolecular Nomenclature, which is now the leading nomenclature body in the polymer field. The Commission is promulgating a series of rules and definitions that are placing polymer nomenclature on a much more systematic basis than had previously been the case (Table 1) (1–21). The International Standardization Organization (ISO), primarily through its Technical Committee TC/61 Plastics, and various national nomenclature bodies (such as that of the American Chemical Society) are also helping to shape the field. Recent issues of *Chemical Abstracts* are additional authoritative sources of polymer nomenclature.

At the present time, the IUPAC Commission on Macromolecular Nomenclature is developing a set of definitions for many of the basic terms dealing with polymer molecules, assemblies of polymer molecules, polymer solutions, polymer crystals, polymer melts and solids, polymerization reactions, etc. It is also extending existing nomenclature to more complicated cases, such as cross-linked polymers. When this phase of the work is completed by the late 1980s, the naming of polymers and polymer terminology will have become largely systematized and, following the IUPAC practice in other fields of chemistry, a compendium of polymer nomenclature rules will be published.

**Table 1. IUPAC Publications on Polymer Nomenclature**

| Title | Comment | Refs. |
|---|---|---|
| Report on Nomenclature in the Field of Macromolecules | obsolete | 1 |
| Report on Nomenclature Dealing with Steric Regularity in High Polymers | superseded by Ref. 2 | 3 |
| Revised Report on Nomenclature Dealing with Steric Regularity in High Polymers | superseded by Ref. 4 | 2,5 |
| Report of the Committee on Nomenclature of the International Commission on Macromolecules | obsolete | 6 |
| Basic Definitions of Terms Relating to Polymers | | 7,8 |
| List of Standard Abbreviations (Symbols) for Synthetic Polymers and Polymer Materials (1974) | superseded by Ref. 9 | 10 |
| Use of Abbreviations for Names of Polymeric Substances | Recommendations 1986 | 9 |
| Nomenclature of Regular Single-Strand Organic Polymers | | 11 |
| Stereochemical Definitions and Notations Relating to Polymers | Provisional<br>Recommendations 1980 | 12<br>4 |
| Nomenclature for Regular Single-Strand and Quasi Single-Strand Inorganic and Coordination Polymers | Provisional<br>Recommendations 1984 | 13<br>14 |
| Note on the Terminology for Molar Masses in Polymer Science | | 15–17 |
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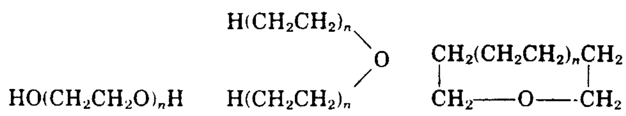
## Basic Definitions

No nomenclature document is more fundamental to a given science than the definitions of basic terms used in that area. The IUPAC Commission on Macromolecular Nomenclature published a document in 1974 (8) that offers definitions of 52 terms, including polymer, constitutional unit, monomer, polymerization, regular polymer, tactic polymer, block polymer, graft polymer, monomeric unit, degree of polymerization, addition polymerization, condensation polymerization, homopolymer, copolymer, bipolymer, terpolymer, copolymerization, and many others. Both structure-based and process-based definitions are given.

## Source-based Nomenclature

Traditionally, polymers have been named by attaching the prefix poly to the name of the real or assumed monomer (the "source") from which it is derived.

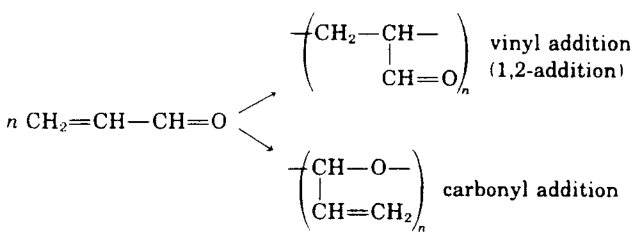
Thus polystyrene is the polymer made from styrene and will often be found in an index under "styrene, polymer of." When the name of the monomer consists of two or more words, parentheses should be used (1), as in poly(vinyl acetate), poly(methyl methacrylate), poly(sodium styrenesulfonate), etc. Failure to use parentheses can lead to ambiguity: polychlorostyrene can be the name of either a polychlorinated (monomeric) styrene molecule or a polymer derived from chlorostyrene; polyethylene oxide can refer to polymer (**1**), polymer (**2**), or the macrocycle (**3**).



(**1**) (**2**) (**3**)

These problems are easily overcome with parentheses; names such as poly(chloro)styrene, poly(chlorostyrene), and poly(ethylene oxide) clearly indicate the part of the name to which the prefix poly refers. The omission of parentheses is, unfortunately, quite common.

The principal deficiency of source-based nomenclature is that the chemical structure of the monomeric unit in a polymer is not identical with that of the monomer, eg, —$CH_2$—CHX— vs $CH_2$=CHX; thus the name polymonomer is actually a misnomer. The structure of the repeating unit is also not specified in is scheme; for example, polyacrolein does not indicate whether the vinyl or the aldehyde group has polymerized (see ACROLEIN POLYMERS).




Different types of polymerization can take place with many other monomers, depending on the polymerization conditions. Furthermore, a name such as poly(vinyl alcohol) refers to a hypothetical source, since this polymer is obtained by hydrolysis of poly(vinyl acetate). In spite of these serious deficiencies, source-based nomenclature is still firmly entrenched in industrial literature and, to a lesser extent, in scientific communication. It originated at a time when polymer science was less developed and the structure of most polymers ill-defined. The rapid advances now being made in structural determination of polymers will gradually shift the emphasis of polymer nomenclature away from starting materials and toward the structure of the macromolecules.

**Copolymers.** Copolymers are polymers that are derived from more than one species of monomer (8). Because this is a process-based definition, source-based nomenclature can be easily adapted to the naming of copolymers (18). However, the arrangement of the various types of monomeric units must be specified. Seven types of arrangements have been defined and are shown in Table where A, B, and C represent the names of monomers. The monomer names e linked through a connective (infix), such as -*co*-, to form the name of the copolymer, as in poly(styrene-*co*-acrylonitrile). The order of citation of the mono-

mers is arbitrary, except for graft copolymers where the backbone monomer is named first.

An equally acceptable alternative scheme utilizes the prefix copoly followed by citation of the names of the monomers used, separated from each other by an oblique stroke. Parentheses are also needed. For example, copoly(styrene/butadiene) denotes an unspecified copolymer of styrene and butadiene. The other connectives of Table 2 are placed before such names to provide additional structural information, as in

*stat*-copoly(styrene/butadiene)
*ran*-copoly(ethylene/vinyl acetate)
*alt*-copoly(styrene/maleic anhydride)
*per*-copoly(ethylene phenylphosphonite/methyl acrylate/carbon dioxide)
*block*-copoly(styrene/butadiene/methyl methacrylate)
*graft*-copoly(styrene/butadiene)

It is not necessary to use parentheses to enclose vinyl acetate, maleic anhydride, methyl acrylate, etc, even though the name of each of these monomers consists of two words; the names of the polymers, as written here, are unambiguous.

The names of copolymers, derived either from the main scheme or the alternative, can be further modified to indicate various structural features. For example, the chemical nature of end groups can be specified as follows:

$\alpha$-X-$\omega$-Y-poly(A-*alt*-B)
$\alpha$-butyl-$\omega$-carboxy-*block*-copoly(styrene/butadiene)

Whereas subscripts placed immediately after the name of the monomer or the block designate the degree of polymerization or repetition, mass and mole fractions and molar masses, which in most cases are average quantities, are expressed by placing corresponding figures after the complete name of the copolymer. The order of citation is as for the monomeric species in the name. Unknown quantities are designated by *a, b,* etc. Some examples follow.

A block copolymer containing 75 mass % of polybutadiene and 25 mass % of polystyrene is

polybutadiene-*block*-polystyrene (0.75:0.25 $w$) or
*block*-copoly(butadiene/styrene) (75:25 mass %)

A graft copolymer, consisting of a polyisoprene backbone grafted with isoprene and acrylonitrile units in an unspecified arrangement, containing 85 mol % of isoprene units and 15 mol % of acrylonitrile units is

polyisoprene-*graft*-poly(isoprene-*co*-acrylonitrile) (0.85:0.15 $x$) or
*graft*-copoly[isoprene/(isoprene;acrylonitrile)] (85:15 mol %)

A graft copolymer consisting of 75 mass % of polybutadiene with a relative molecular mass of 90,000 as the backbone and 25 mass % of polystyrene in grafted chains with a relative molecular mass of 30,000 would be

polybutadiene-*graft*-polystyrene (75:25 mass %; 90,000:30,000 $M_r$)

**Table 2. IUPAC Nomenclature of Copolymers[a]**

| Type | Arrangement of monomeric units | Structure | Connective | Example |
|---|---|---|---|---|
| unspecified | unknown or unspecified | (A-*co*-B) | -*co*- | poly[styrene-*co*-(methyl methacrylate)] |
| statistical | obeys known statistical laws | (A-*stat*-B) | -*stat*- | poly(styrene-*stat*-acrylonitrile-*stat*-butadiene) |
| random | obeys Bernoullian statistics | (A-*ran*-B) | -*ran*- | poly[ethylene-*ran*-(vinyl acetate)] |
| alternating | alternating sequence | $(AB)_n$ | -*alt*- | poly[(ethylene glycol)-*alt*-(terephthalic acid)] |
| periodic | periodic with respect to at least three monomeric units | $(ABC)_n$<br>$(ABB)_n$<br>$(AABB)_n$<br>$(ABAC)_n$ | -*per*- | poly[formaldehyde-*per*-(ethylene oxide)-*per*-(ethylene oxide)] |
| block | linear arrangement of blocks | —AAAAA—BBBBBB— | -*block*-[b] | polystyrene-*block*-polybutadiene |
| graft | polymeric side chain different from main chain[c] | —AAAAAAAAAAAA—<br>B<br>B<br>B<br>B<br>B | -*graft*-[d] | polybutadiene-*graft*-polystyrene |

[a] Main system of the IUPAC document (18); an alternative scheme is described in the text.
[b] The connective -*b*- has also been used.
[c] Main chain (or backbone) is specified first in the name.
[d] The connective -*g*- has also been used.

A graft copolymer in which the polybutadiene backbone has a DP of 1700 and the polystyrene grafts have an unknown DP is named

*graft*-copoly(butadiene/styrene) (1700:*a* DP)

The published IUPAC copolymer document (18) should be consulted for the names of more complex copolymers, eg, those having a multiplicity of grafts or having chains radiating from a central atom (see also BLOCK COPOLYMERS; COPOLYMERS, ALTERNATING; COPOLYMERIZATION; GRAFT COPOLYMERS).

## Structure-based Nomenclature

For organic polymers that are regular, ie, have only one species of constitutional unit in a single sequential arrangement, and consist only of single strands, the IUPAC has promulgated a structure-based system of naming polymers (11). As originally devised by the Polymer Nomenclature Committee of the American Chemical Society (22), it consists of naming a polymer as poly(constitutional repeating unit), wherein the repeating unit is named as a bivalent organic radical according to the usual nomenclature rules for organic chemistry. It is important to note that in structure-based nomenclature the name of the constitutional repeating unit has no relationship to the source from which the unit was prepared. The name is simply that of the largest identifiable unit in the polymer, and locants for unsaturation, substituents, etc are dictated by the structure of the unit.

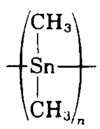
The steps involved in naming the constitutional repeating unit are (*1*) identification of the unit, taking into account the kinds of atoms in the main chain and the location of substituents; (*2*) orientation of the unit; and (*3*) naming of the unit. Examples of names for some common polymers are given in Table 3. Note that in this system parentheses are always used to enclose the repeating unit.

Structure-based nomenclature can be utilized to name polymers with great complexity, provided only that they be regular and single-stranded. Among these are polymers with constitutional repeating units which consist, themselves, of a series of smaller subunits; polymers with heteroatoms or heterocyclic ring systems in the main chain; and polymers with substituents on acyclic or cyclic subunits of constitutional repeating units. Structure-based nomenclature is also applicable to copolymers having a regular structure, regardless of the starting materials used, eg, poly(oxyethyleneoxyterephthaloyl). In principle, it should be possible to extend the existing structure-based nomenclature beyond regular, single-strand polymers to polymers that have reacted, cross-linked polymers, ladder polymers, and other more complicated systems.

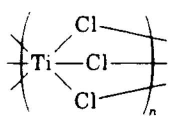
Structure-based nomenclature has gained acceptance in the scientific literature, eg, *Chemical Abstracts*, because it overcomes many of the deficiencies of source-based nomenclature.

**Inorganic and Coordination Polymers.** The nomenclature of regular single-strand inorganic and coordination polymers (qv) is governed by the same

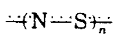
ındamental principles as that for single-strand organic polymers (14). The name ˋ such a polymer is that of the smallest structural repeating unit prefixed by ıe terms poly, *catena* (for linear chains) or other structural indicator, and des-nations for end groups. The structural units are named by the nomenclature ıles for inorganic and coordination chemistry. Some examples are



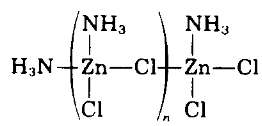
*catena*-poly[dimethyltin]



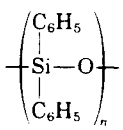
*catena*-poly[titanium-tri-$\mu$-chloro]



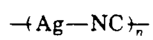
*catena*-poly[nitrogen-$\mu$-thio]



$\alpha$-ammine-$\omega$-(amminedichlorozinc)-*catena*-poly[(amminechlorozinc)-$\mu$-chloro]



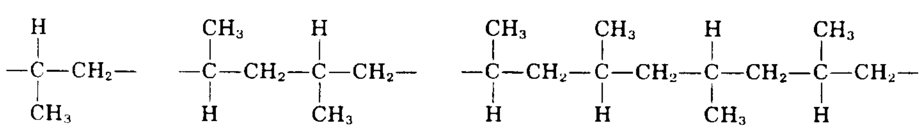
*catena*-poly[(diphenylsilicon)-$\mu$-oxo]



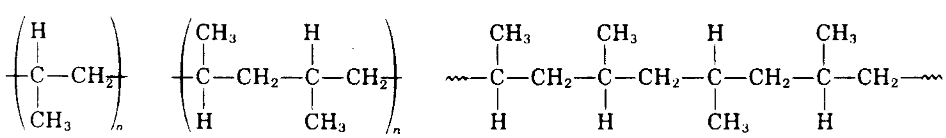
*catena*-poly[silver-$\mu$-(cyano-*N*:*C*)]

**.ereochemical Definitions and Notations.** Structure-based nomenclature regular polymers (4) can denote stereochemical features if the repeating unit ıed is the configurational unit, ie, a constitutional unit having one or more sites defined stereoisomerism (8). Structure-based names are then derived in the ıual fashion. The various stereochemical features that are possible in a polymer ust be defined.

Natta and co-workers introduced the concept of tacticity, ie, the orderliness the succession of configurational repeating units in the main chain of a polymer. ır example, in poly(propylene), possible steric arrangements are shown in Fischer ojections displayed horizontally:



.d the corresponding polymers have the following structures:

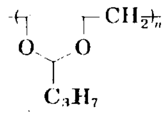
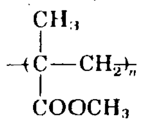
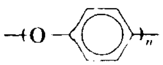
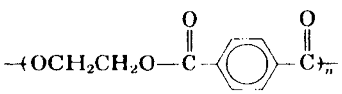
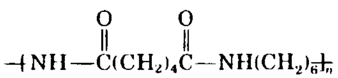
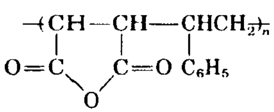


isotactic syndiotactic atactic

The isotactic polymer has only one species of configurational unit in a single ʇuential arrangement and the syndiotactic polymer shows an alternation of ıf ational units that are enantiomeric, whereas in the atactic polymer the

**Table 3. Examples of Systematic Structure-based Names for Polymers[a]**

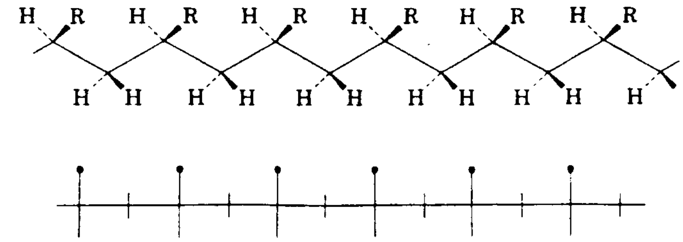
| Structure | Structure-based name | Common (source-based) name |
|---|---|---|
| $-(CH_2CH_2)_n-$ | poly(methylene) | polyethylene |
| $-(\underset{\lvert \atop CH_3}{CH}CH_2)_n-$ | poly(propylene) | polypropylene |
| $-(\overset{CH_3 \atop \lvert}{\underset{\lvert \atop CH_3}{C}}-CH_2)_n-$ | poly(1,1-dimethylethylene) | polyisobutylene |
| $-(\overset{CH_3 \atop \lvert}{C}=CHCH_2CH_2)_n-$ | poly(1-methyl-1-butenylene) | polyisoprene |
| $-(\underset{\lvert \atop C_6H_5}{CH}CH_2)_n-$ | poly(1-phenylethylene) | polystyrene |
| $-(\underset{\lvert \atop Cl}{CH}CH_2)_n-$ | poly(1-chloroethylene) | poly(vinyl chloride) |
| $-(\underset{\lvert \atop CN}{CH}CH_2)_n-$ | poly(1-cyanoethylene) | polyacrylonitrile |
| $-(\underset{\lvert \atop OOCCH_3}{CH}CH_2)_n-$ | poly(1-acetoxyethylene) | poly(vinyl acetate) |
| $-(\overset{F \atop \lvert}{\underset{\lvert \atop F}{C}}CH_2)_n-$ | poly(1,1-difluoroethylene) | poly(vinylidene fluoride) |

| | | |
|---|---|---|
| $-(CF_2)_n-$ | poly(difluoromethylene) | polytetrafluoroethylene |
|  | poly[(2-propyl-1,3-dioxane-4,6-diyl)methyle...] | poly(vinyl butyral) |
|  | poly[1-(methoxycarbonyl)-1-methylethylene] | poly(methyl methacrylate) |
| $-(OCH_2CH_2)_n-$ | poly(oxyethylene) | poly(ethylene oxide) |
|  | poly(oxy-1,4-phenylene) | poly(phenylene oxide) |
|  | poly(oxyethyleneoxyterephthaloyl) | poly(ethylene terephthalate) |
|  | poly(iminoadipoyliminohexamethylene) | poly(hexamethylenediamine-*co*-adipic acid) or poly(hexamethylene adipamide) |
|  | poly[2,5-dioxotetrahydrofuran-3,4-diyl(phenylethylene)] | poly(maleic anhydride-*co*-styrene) |

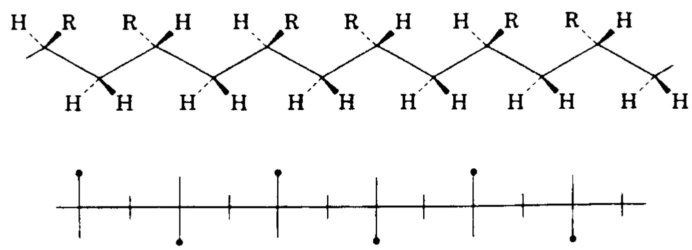
[a] Ref. 6. Courtesy of *Pure and Applied Chemistry*.

molecules have equal numbers of the possible configurational units in a random sequence distribution. This can be generalized as follows:

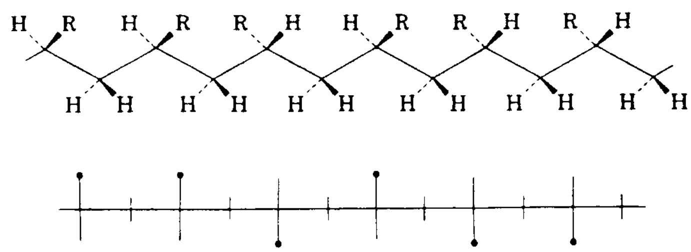
*Isotactic:*



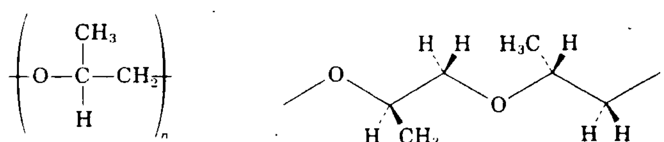
*Syndiotactic:*



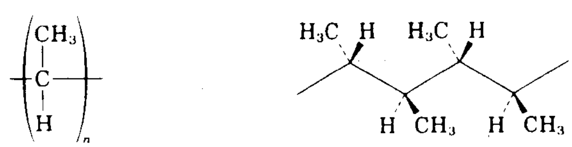
*Atactic:*



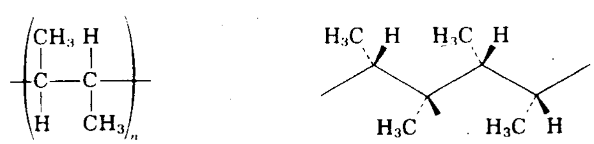
Further examples of tactic polymers are



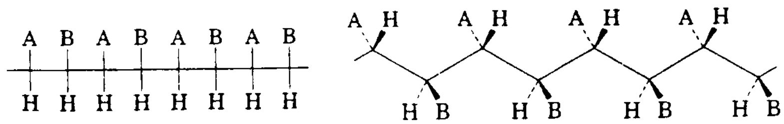
isotactic poly(oxypropylene)



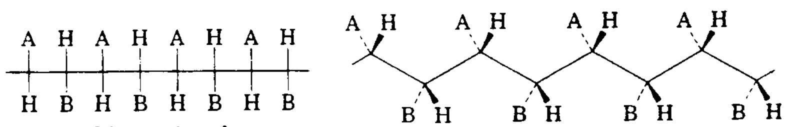
isotactic poly(ethylidene)



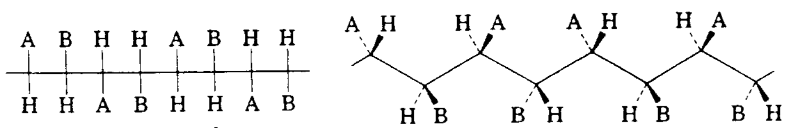
syndiotactic poly(ethylidene)



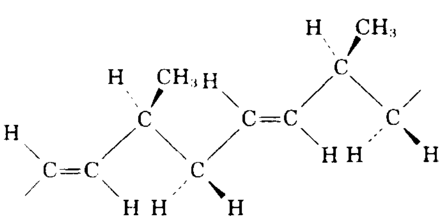
erythrodiisotactic polymer



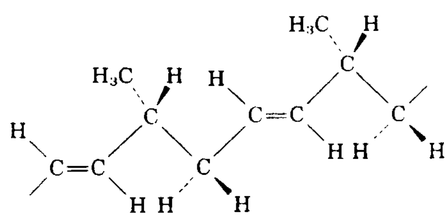
threodiisotactic polymer



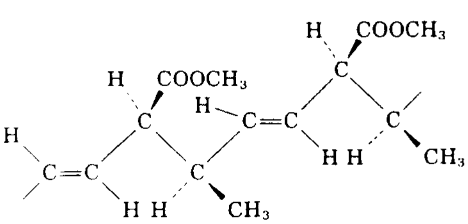
disyndiotactic polymer



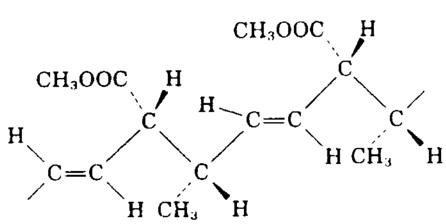
and/or



isotactic poly(3-methyl-*trans*-1-butenylene) or transisotactic poly(3-methyl-1-butenylene)

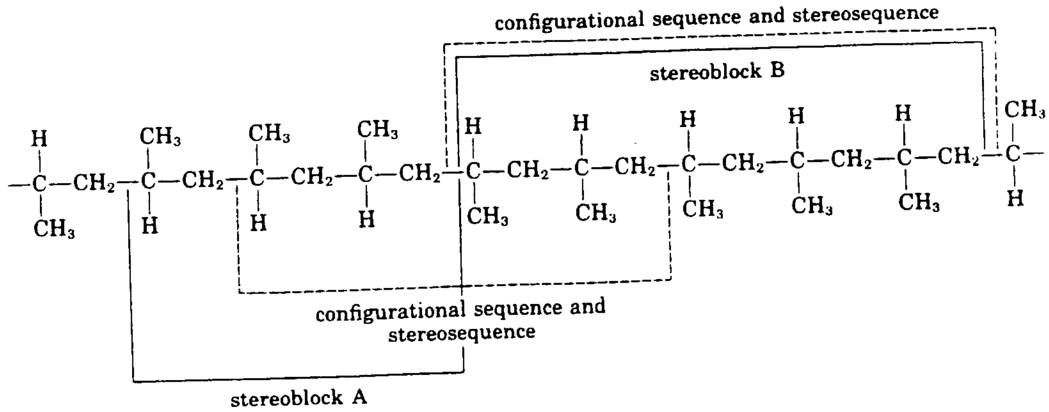


and/or



diisotactic poly[*threo*-3(methoxycarbonyl)-4-methyl-*trans*-1-butenylene] or transthreodiisotactic poly[3-(methoxycarbonyl)-4-methyl-1-butenylene]

The concept of a stereoblock is illustrated in the following example of a regular poly(propylene) chain, in which the stereoblocks are denoted by ⌐¬. The sequence of identical relative configurations of adjacent units that characterizes a stereoblock is terminated at each end of the block. The dashed line ... encloses a configurational sequence, which may or may not be identical ... a stereoblock.




The published IUPAC document (4) should be consulted for more complex cases and for the notations used to designate conformations of polymer molecules (bond lengths, bond angles, torsion angles, helix sense, isomorphous and enantiomorphous structures, line repetition groups and symmetry elements, etc) as well as for the various stereochemical definitions (see also MICROSTRUCTURE; STEREOREGULAR POLYMERS).

## Trade Names and Abbreviations

Because the systematic names of polymers can be cumbersome, trade names and abbreviations are frequently used as a shortcut in industrial literature and

**Table 4. List of Abbreviations from the 1986 IUPAC Recommendations[a]**

| | |
|---|---|
| PAN | polyacrylonitrile |
| PCTFE | polychlorotrifluoroethylene |
| PEO | poly(ethylene oxide) |
| PETP[b] | poly(ethylene terephthalate) |
| PE | polyethylene |
| PIB | polyisobutylene |
| PMMA | poly(methyl methacrylate) |
| POM | poly(oxymethylene); polyformaldehyde |
| PP | polypropylene |
| PS | polystyrene |
| PTFE | polytetrafluoroethylene |
| PVAC | poly(vinyl acetate) |
| PVAL | poly(vinyl alcohol) |
| PVC | poly(vinyl chloride) |
| PVDC | poly(vinylidene dichloride) |
| PVDF | poly(vinylidene difluoride) |
| PVF | poly(vinyl fluoride) |

[a] Ref. 9.
[b] The abbreviation PET is commonly used in the literature.

oral communication. For example, the simpler generic name nylon-6,6 for a polyamide, where the first number refers to the number of carbon atoms of the diamine and the second number to that of the diacid fragment, appears often in the literature rather than the systematic name poly(iminoadipoyliminohexamethylene). Useful compilations of trade names for polymers can be found in Refs. 23 and 24.

Perhaps the most widely used shortcut is the use of abbreviations for common industrial polymeric materials. The IUPAC recognizes that there may be advantages in some cases to use abbreviations, but urges that each abbreviation be fully defined the first time it appears in the text and that no abbreviation be used in titles of publications. Because there are inherent difficulties in assigning systematic and unique abbreviations to polymeric structures, only a short list has the IUPAC's official sanction (9,10) (Table 4). ISO has published a more extensive list (25), and the American Chemical Society has compiled a master list of all known abbreviations in the polymer field (26).

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**NONAQUEOUS DISPERSIONS.** See COATINGS.

**NONCOMBUSTIBLE FABRICS.** See FLAMMABILITY.

**NONDESTRUCTIVE TESTING.** See TEST METHODS.

**NON-NEWTONIAN FLOW.** See VISCOELASTICITY.

## NONWOVEN FABRICS



### SURVEY

Nonwoven fabrics are porous, textilelike materials, usually in flat she form, composed primarily or entirely of fibers assembled in webs (1–3). The fabrics, also called bonded fabrics, formed fabrics, or engineered fabrics, are ma ufactured by processes other than spinning, weaving, or knitting. The thickn of the sheets may vary from 25 $\mu$m to several centimeters, and the weight fr 10 g/m$^2$ to 1 kg/m$^2$. A sheet may resemble paper or a woven or knitted fabric appearance and may have a unique texture or pattern. It may be as compact a crisp as paper or supple and drapable as a conventional textile; it may be resili or limp. Its tensile properties may be barely self-sustaining or so high that i impossible to tear, abrade, or damage the sheet by hand. The fiber compone one or several types, may be natural or synthetic, from 1–3-mm long to endl The tensile properties may depend on frictional forces or a film-forming polym additive functioning as an adhesive binder. All or some of the fibers may welded by heat or solvent. A scrim, gauze, netting, yarn, or other conventi sheet material may be added to one or both faces, or embedded within as r forcement. The nonwoven fabric may be incorporated as a component in a c posite structure.

Felted fabrics from animal hairs, eg, wool (qv), are not included even th

**an·hy·drous** \(ˈ)anˈhīdrəs\ *adj* [modif. (influenced by *hydr-*, *hydro-*) of Gk *anydros* waterless, fr. *an-* + *-ydros* (fr. *hydōr* water) — more at WATER] **:** destitute of water — used of water of crystallization, dissolved or combined water, adsorbed water

# EXHIBIT 17

 DISK ENCLOSED



UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. No. 04-12457 PBS

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ORIGINAL

DePUY MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

v.

ARTHREX INC.,

A Delaware Corporation,

Defendants.

------------------------------x

DEPOSITION OF MATTHEW GOODWIN

New Brunswick, New Jersey

January 17, 2006

Reported by:

MARY F. BOWMAN, RPR, CRR

JOB NO.: SE 173

GOODWIN

you.

A. The novelty is set forth I think most aptly in the summary of invention. "Surprisingly, the heterogeneous braids which exhibit a combination of outstanding properties attributable to the specific property of the dissimilar fiber-forming materials which make up the braided yarns." Just reading further down, "It is possible to taylor the physical and biological properties of the braid by varying the type and proportion of the each of the dissimilar fiber-forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids without sacrificing physical strength or knot security."

Upon my reading of the '446 patent, that summarizes the novelty of the invention.

**Q. I ask you to turn to Exhibit 3. I think it is the other portion of the prosecution history.**